



# Applications for Community Oncology

*Nurse Symposium*

October 26, 2023





**wellCORNER**™  
A Cornerstone Specialty Network Company





70%

Patients indicated they use complementary or alternative medicines as part of their cancer care; of them 42% use it to manage their symptoms



70%

Of patients learned of complementary and alternative medicines from sources *other than* their health care providers



30%

indicated that they did not inform their treating oncologist about complementary and alternative medicines they are taking

**Patients are utilizing complementary and alternative medicines, and over 80% view their health care providers as a trustworthy source of information**



**wellCORNER provides a solution. A website with medically reviewed products and education to which HCPs can refer their patients**

**wellCORNER's mission is to provide access to science-based, high-quality products that are specifically designed to help cancer patients and their caregivers.**



## **KEY BENEFITS for Patients**

- ✓ Access to natural, high-quality products that are scientifically formulated for cancer patients
- ✓ Products available through wellCORNER offer patients a lower retail price
- ✓ Receive medically reviewed education about products and their purpose



## **KEY BENEFITS for Practices**

### ***Medically Reviewed Products and Education***

- Aromatherapy
- Cold therapy
- Multivitamins
- Skincare
- Nausea Relief Bracelets

### ***Provided to patients at point-of-care***

- Website accessible via all mobile devices
- Marketing materials provided to oncology practices for distribution






### ***Turn-key Solution for Practice***

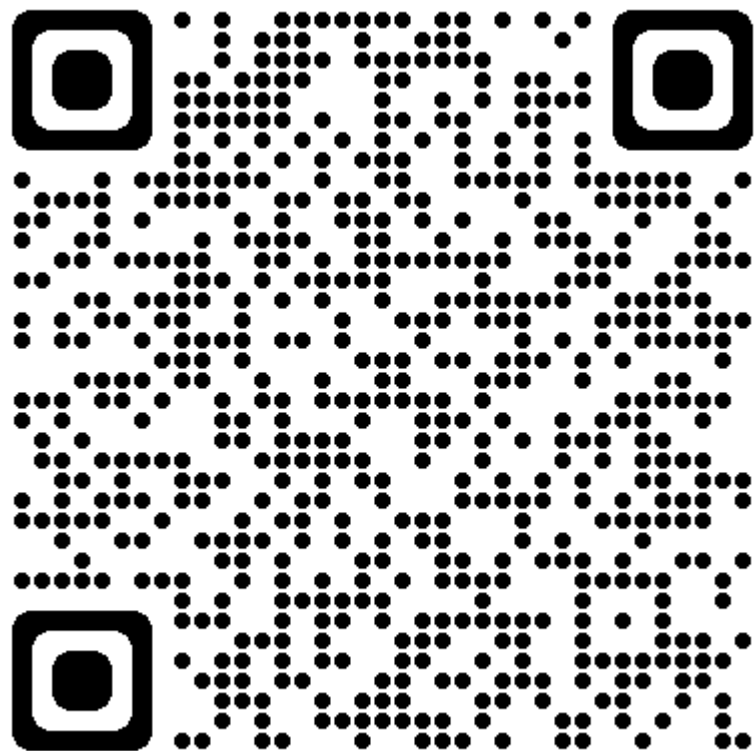
- Products shipped direct to patient, practice does not house inventory
- wellCORNER team connects with practice advocates

## **KEY BENEFITS for Patients**

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# Product Lines

Product Line	Supplier	Products
<b>Aromatherapy</b>	Wyndmere Naturals	<ul style="list-style-type: none"> <li>• Essential Oils</li> <li>• Inhalers</li> <li>• Patches</li> <li>• Diffusers</li> </ul> 
<b>Cold Therapy</b>	ReliefGenius	<ul style="list-style-type: none"> <li>• Cold Glove Bundle</li> <li>• Cold Sock Bundle</li> </ul> 
<b>Skincare</b>	LindiSkin	<ul style="list-style-type: none"> <li>• Lotions</li> <li>• Washers</li> <li>• Cooling wraps / rolls</li> </ul> 
<b>Multi-vitamins</b>	4CancerWellness	<ul style="list-style-type: none"> <li>• SafeVite multi-vitamin</li> <li>• 4Bones</li> </ul> 
<b>Nausea Relief Bracelets</b>	Blisslets	<ul style="list-style-type: none"> <li>• Stylish acupressure bracelets</li> </ul> 



[www.wellCORNER.com](http://www.wellCORNER.com)





OCTOBER

BREAST CANCER

AWARENESS MONTH

# Breast Cancer Overview And Health Related Disparities

Dr. Maya Leiva

# Breast Cancer Overview

**1 in 8 AFAB** in the United States will be diagnosed with breast cancer in their lifetime  
When caught in its earliest, localized stages, **the 5-year relative survival rate is 99%**

## **EARLY DETECTION**

- Breast Lump
- Breast Pain
- Breast Cyst
- Breast Self-Exam
- Clinical Breast Exam
- Mammogram

## **DIAGNOSIS**

- Diagnostic Mammogram
- Ultrasound
- MRI
- Breast Biopsy
- Lab Tests

## **STAGES**

- Stages 0 & 1
- Stage 2 (II) And Stage 2A (IIA)
- Stage 3 (III) A, B, And C
- Stage 4 (IV) Breast Cancer

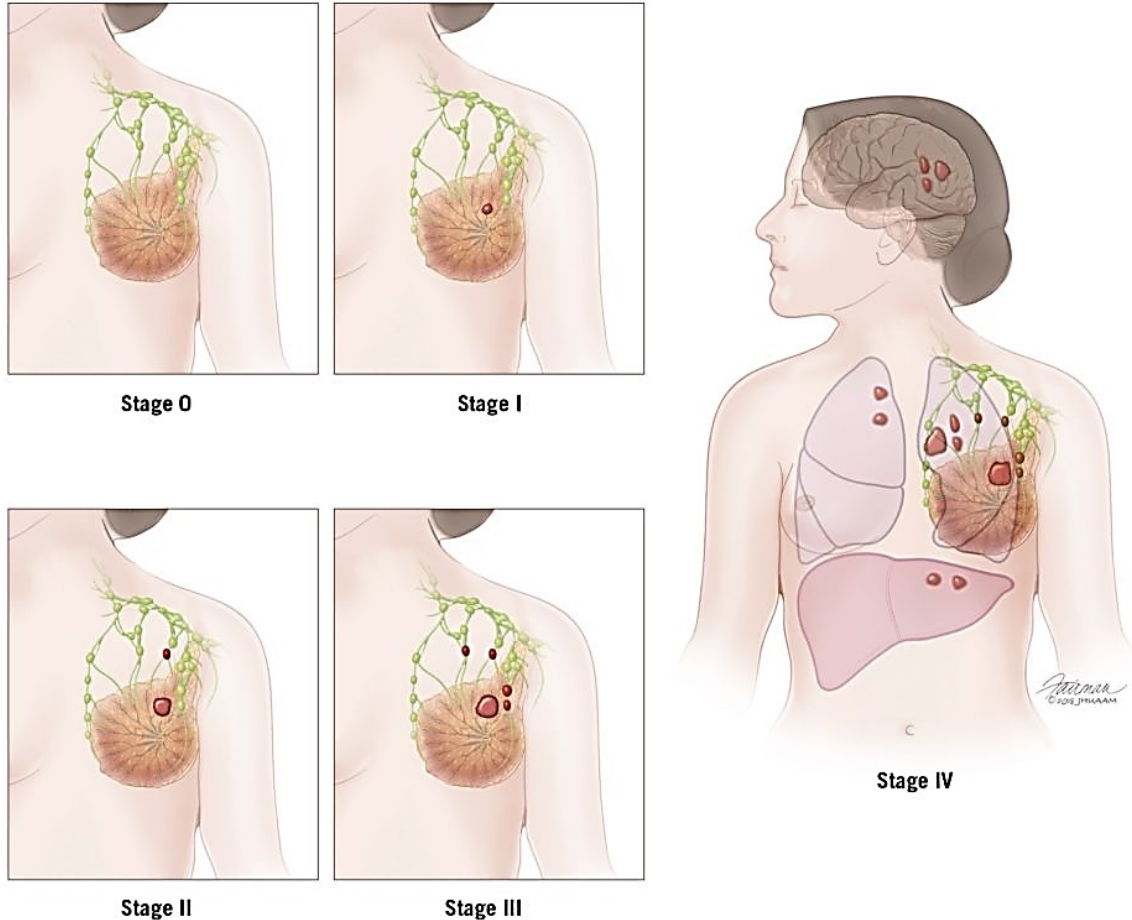
## **TYPES OF BREAST CANCER**

- Ductal Carcinoma In Situ (DCIS)
- Invasive Ductal Carcinoma (IDC)
- Lobular Carcinoma In Situ (LCIS)
- Invasive Lobular Cancer (ILC)
- Triple Negative Breast Cancer
- Inflammatory Breast Cancer (IBC)
- Metastatic Breast Cancer
- Breast Cancer During Pregnancy
- Other Types

## **TREATMENT**

- Surgery
- Lumpectomy
- Mastectomy
- Lymph Node Removal & Lymphedema
- Breast Reconstruction
- Chemotherapy
- Radiation Therapy
- Hormone Therapy
- Targeted Therapy
- Standard Treatment vs. Clinical Trials

# Stages of Breast Cancer



Staging & Grade - Breast Pathology | Johns Hopkins Pathology (jhu.edu)

# Characteristics of Breast Cancer Molecular Subtypes

Molecular subtype	Luminal A	Luminal B	HER2	TNBC
ER/PR	+		-	
HER2	-	+	-	
Frequency <sup>a</sup>	50-60%	30%	10%	10-20%
Grade <sup>b</sup>	Low		High	
Prognosis <sup>c</sup>	Good		Poor	
5-y survival rate <sup>d</sup>	94.3%	90.5%	84.0%	76.9%
Treatment	Endocrine therapy		Anti-HER2 therapy	
	Chemotherapy			

Burguin, A.; Diorio, C.; Durocher, F. Breast Cancer Treatments: Updates and New Challenges. J. Pers. Med. 2021, 11, 808.

# Social Determinants of Health



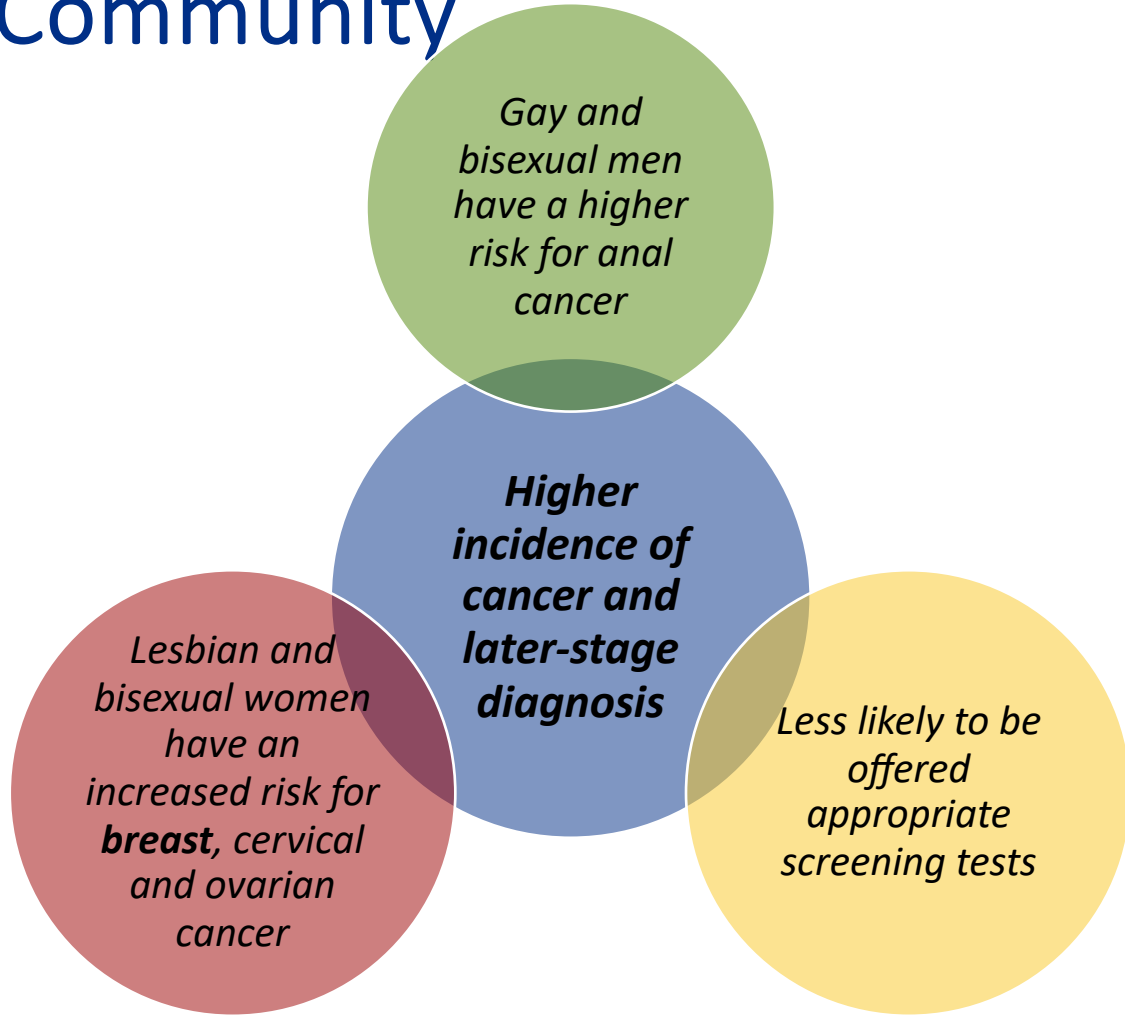
Social determinants of health (SDOH) have a major impact on people's health, well-being, and quality of life.

Examples of SDOH include:

- Safe housing, transportation, and neighborhoods
- Racism, discrimination, and violence
- Education, job opportunities, and income
- Access to nutritious foods and physical activity opportunities
- Polluted air and water
- Language and literacy skills

[Social Determinants of Health - Healthy People 2030 | health.gov](https://www.health.gov/healthypeople/2030/social-determinants-of-health)

# Cancer and Health Related Disparities in the LGBTQ+ Community



Collect sexual orientation and gender identity (SOGI) data

- Promote patient centered care
- Ask all patients how they identify

Advise cancer screening based on organs

- Provide education on organ based screening and not gender identity or sexual orientation

Don't make assumptions

- Gender affirming surgery does not mean that they have or do not have certain organs

# Breast Cancer in the LGBTQ+ Community

**Breast  
Cancer  
has no  
gender**

Smoking, alcohol consumption, obesity, and fewer pregnancies increase risk

Trans women are at higher risk for breast cancer due to receiving hormone therapy

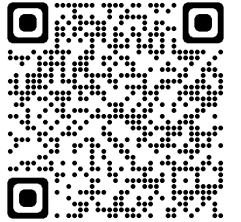
A mammogram cancer screening can be very emotionally, mentally, and physically distressing

After a mastectomy there is still some breast tissue, a lump or bump should still be worked up

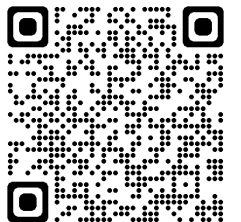
**cornerstone**  
specialty network™

## LGBTQ+ clinical competency training resources:

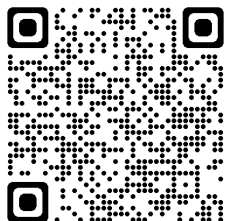
[Home » LGBTQIA+ Health Education Center](#)



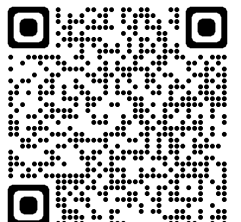
[Home - GLMA: Health Professionals  
Advancing LGBTQ Equality](#)



[- National LGBT Cancer Network \(cancer-  
network.org\)](#)



[Welcoming Spaces | Society of Gynecologic  
Oncology \(sgo.org\)](#)



# Breast Cancer in the LGBTQ+ Community

## *Be inclusive*

Pronoun badges on IDs, rainbow pins or ribbons, or sharing our pronouns when entering a room before asking a patient's

Recognize LGBTQ+ individuals form strong "families of choice" beyond their families of origin

Awareness of language and color association is key when communicating with LGBTQ+ patients in order to provide a comfortable environment

Provide education and resources to team members on cancer risks, prevention, screening, and treatment unique to LGBTQ+ patients

*"I'm your nurse, Jennifer, and my pronouns are she/her," followed by asking the patient, "And you are?"*

*Instead of asking, "Is this your mother?," it is less presumptive to ask, "Who is here with you today?"*

*"Have you had gender-affirming surgery?" (often referred to as "top" or "bottom" surgery)*

# Antibody Drug Conjugates And Managing Side Effects

Katie Alexander

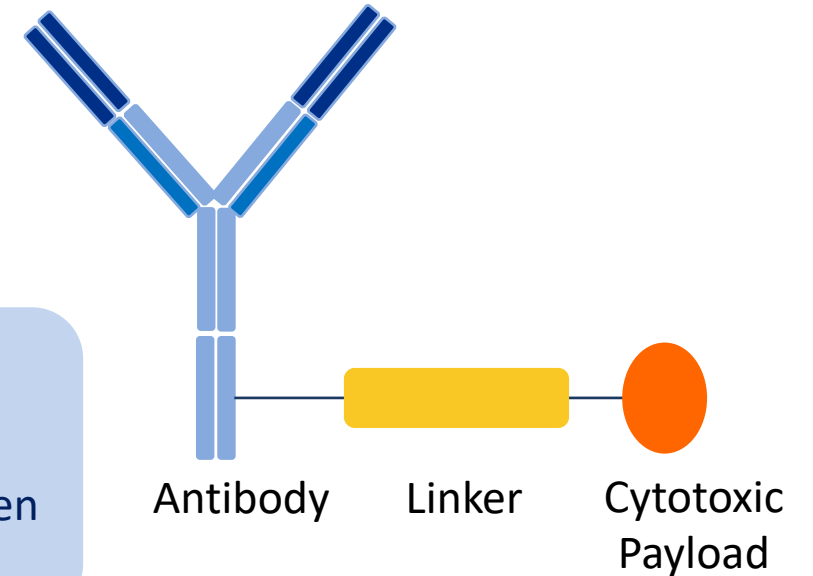


# The ABCs of ADCs

**A**ntibody specific targeting delivers the cytotoxic payload or drug to the site of the tumor cells; increased efficacy and reduced systemic exposure and toxicity

**B**ystander effect occurs where cells within close proximity of the targeted cancer cells are exposed to the antitumor effects of ADCs, irrespective of antigen expression

**C**leavage of the linker occurs once internalized in the tumor cell and releases the cytotoxic payload, promoting tumor cell death; drug–antibody ratio (DAR), defined as the number of payload molecules that can be attached to the antibody, influences the potency and therapeutic index of ADCs



# Current FDA Approved Antibody Drug Conjugates (ADCs)

*ADCs consist of a monoclonal antibody linked to a biologically active cytotoxic payload or drug*

## **SOLID TUMOR ADCs**

- Trastuzumab emtansine (KADCYLA®)
- Trastuzumab deruxtecan (ENHERTU®)
- Enfortumab vedotin (PADCEV®)
- Sacituzumab govitecan (TRODELVY®)
- Mirvetuximab soravtansine-gynx (ELAHERE™)

Breast Cancer  
Non-Small Cell Lung Cancer (NSCLC)  
Gastric or Gastroesophageal Junction Adenocarcinoma  
Urothelial Cancer  
FR $\alpha$  positive, platinum-resistant epithelial Ovarian, Fallopian tube, or Primary Peritoneal Cancer

## **HEMATOLOGICAL ADCs**

- Gemtuzumab ozogamicin (MYLOTARG®)
- Brentuximab vedotin (ADCETRIS®)
- Inotuzumab ozogamicin (BESPONSA®)
- Polatuzumab vedotin (POLIVY®)
- Loncastuximab tesirine-lpyl (ZYNLONTA®)

Acute Myeloid Leukemia  
classical Hodgkin lymphoma  
Anaplastic Large Cell Lymphoma  
Diffuse Large B-Cell Lymphoma, not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma

# Box Warnings\* and Warnings and Precautions

## ENHERTU®

- **Interstitial lung disease (ILD) and pneumonitis\***
- Neutropenia
- Left ventricular dysfunction

## TRODELVY®

- **Neutropenia\***
- **Diarrhea\***
- Hypersensitivity and Infusion-related reactions
- Nausea/Vomiting

## KADCYLA®

- **Hepatotoxicity\***
- **Left ventricular ejection fraction\***
- Pulmonary toxicity
- Infusion-Related Reactions
- Hemorrhage
- Thrombocytopenia
- Neurotoxicity

## PADCEV®

- **Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)\***
- Hyperglycemia
- Pneumonitis/Interstitial Lung Disease (ILD)
- Peripheral Neuropathy
- Ocular Disorders
- Infusion Site Extravasation

## ADCETRIS®

- **Progressive multifocal leukoencephalopathy (pml)\***
- Peripheral neuropathy
- Anaphylaxis and infusion reactions
- Hematologic toxicities
- Serious infections and opportunistic infections
- Tumor lysis syndrome
- Hepatotoxicity
- Pulmonary toxicity
- Serious dermatologic reactions
- Gastrointestinal complications
- Hyperglycemia

## ELAHERE™

- **Severe ocular toxicities\***
- Pneumonitis
- Peripheral Neuropathy

## BESPONSA®

- **Hepatotoxicity\***
- Myelosuppression
- Infusion related reactions
- QT interval prolongation

## MYLOTARG®

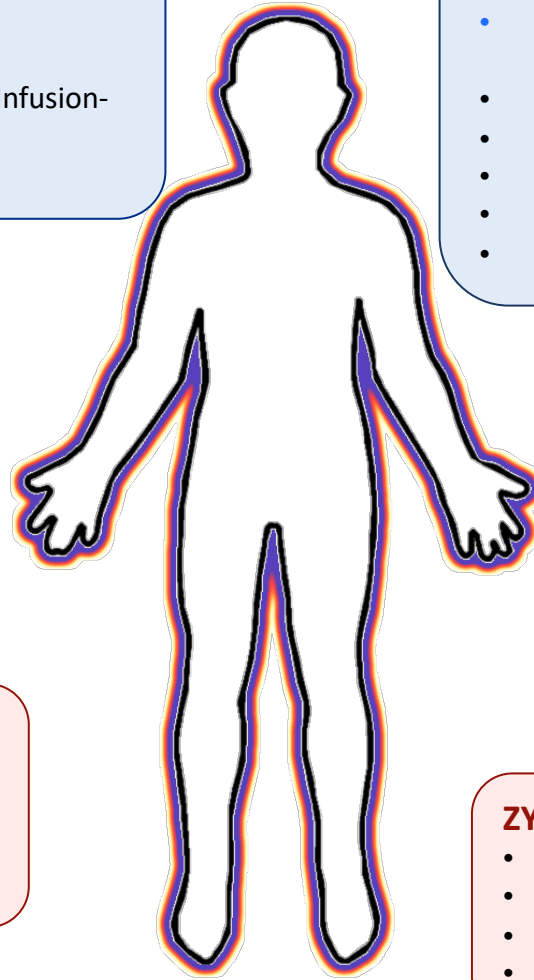
- **Hepatotoxicity\***
- Infusion related reactions
- Hemorrhage

## ZYNLONTA®

- Effusion and Edema
- Myelosuppression
- Infections
- Cutaneous Reactions

## POLIVY®

- Peripheral Neuropathy
- Infusion-Related Reactions
- Myelosuppression
- Serious and Opportunistic Infections
- Progressive Multifocal Leukoencephalopathy (PML)
- Tumor Lysis Syndrome
- Hepatotoxicity



# ADC Patient Education

Prior to initiating treatment, counsel patients and caregivers on the warning signs and symptoms.

Inform patients of existing educational resources:

- [Support and Resources for Patients and Caregivers | ENHERTU® \(fam-trastuzumab deruxtecan-nxki\) \(enhertuhcp.com\)](#)
- [Resources for TRODELVY® \(sacituzumab govitecan-hziy\) | Official HCP Site \(trodelvyhcp.com\)](#)
- [KADCYLA® \(ado-trastuzumab emtansine\) Printable Resources \(kadcyala-hcp.com\)](#)
- [PADCEV® \(enfortumab vedotin-ejfv\) Resources](#)
- [Practice and Patient Support | ELAHERE™ \(mirvetuximab soravtansine-gynx\) \(elaherehcp.com\)](#)
- [Resources for You & Your Patients - ADCETRIS® \(brentuximab vedotin\) HCP Site \(adcetrispro.com\)](#)
- [Materials \(pfizerpro.com\) - BESPONSA®](#)
- [POLIVY® \(polatuzumab vedotin-piiq\) Practice Printable Resources \(polivy-hcp.com\)](#)
- [Patient Support | ZYNLONTA® \(loncastuximab tesirine-lpyl\) HCP Site \(zynlontahcp.com\)](#)

**Setting Our Sights on Living Longer**

People who were treated only with PADCEV® demonstrated a median overall survival of 13 months versus 9 months with chemotherapy. This was based on a study of 608 adults with advanced bladder cancer who previously received immunotherapy medicine and cisplatin- or carboplatin-containing chemotherapy.

**WHAT IS PADCEV?**  
 PADCEV is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery.

- PADCEV may be used alone if you:
  - have received an immunotherapy medicine and chemotherapy that contains platinum, or
  - are not able to receive a chemotherapy that contains the medicine cisplatin and you have received 1 or more prior therapy.
- PADCEV may be used with pembrolizumab (also known as Keytruda®) if you:
  - are not able to receive a chemotherapy that contains the medicine cisplatin.

It is not known if PADCEV is safe and effective in children.  
 PADCEV with pembrolizumab was FDA approved based on a clinical study that measured how many people had a tumor response. There is another study of PADCEV with pembrolizumab ongoing to confirm the clinical benefit.

**SELECT SAFETY INFORMATION**  
 PADCEV may cause serious side effects, including:  
**Skin reactions.** Skin reactions including severe skin reactions have happened in people treated with PADCEV and may be more common when PADCEV is given with pembrolizumab. In some cases, these severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:

- target lesions (skin reactions that look like rings)
- rash or itching that continues to get worse
- blistering or peeling of the skin
- painful sores or ulcers in mouth or nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes

Please see Important Safety Information throughout and read the Patient Information for more information, including risk of Serious Side Effects.

**PADCEV**  
 enfortumab vedotin-ejfv  
 (enfortumab vedotin) (as a combination with pembrolizumab)

**GRANTED FDA BREAKTHROUGH STATUS.**  
 Approved for adults with HER2-low metastatic breast cancer (mBC) who have received chemotherapy for mBC or who have breast cancer that has come back within 6 months of completing chemotherapy after surgery.

With ENHERTU, **STAND ENCOURAGED**

HER2, human epidermal growth factor receptor 2.

**What is ENHERTU?**  
 ENHERTU is a prescription medicine used to treat adults who have:  
 • HER2-low breast cancer that cannot be removed by surgery or that has spread to other parts of the body.

Every step of your first DLBCL treatment matters.

**PLAN YOUR PATH WITH POLIVY®**

What does POLIVY treat?  
 POLIVY is a prescription medicine used with other medicines (a rituximab product, cyclophosphamide, doxorubicin, and prednisone) as a first treatment for adults who have moderate to high risk diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL).

**Important Safety Information**  
 The serious to fatal side effects of POLIVY treatment include nerve problems in your arms and legs, infusion-related reactions, low blood cell counts, infections, rare and serious brain infections, tumor lysis syndrome, liver problems, and potential harm to your unborn baby.

Please see full [Prescribing Information](#), as well as additional Important Safety Information throughout this brochure.

**POLIVY®**  
 polatuzumab vedotin-piiq  
 (polatuzumab vedotin) (as a combination with rituximab, cyclophosphamide, doxorubicin, and prednisone)

Within 6 months of completing adjuvant chemotherapy, your healthcare provider will perform a test to make sure you are still effective in children.

**FORMATION**  
 Information I should know about ENHERTU? Side effects, including:  
 • Life-threatening or that may lead to death  
 • Trouble breathing or shortness of breath  
 • Fever  
 • Rash  
 • Diarrhea  
 • Stomach pain  
 • Headache  
 • Dizziness  
 • Fatigue  
 • Nausea  
 • Vomiting  
 • Constipation  
 • Pain in your arms and legs  
 • Infection  
 • Low blood cell counts  
 • Liver problems  
 • Potential harm to your unborn baby

**ENHERTU®**  
 fam-trastuzumab deruxtecan-nxki  
 (fam-trastuzumab deruxtecan) (as a combination with trastuzumab)



# Checklist for Oncology Nurses

*Communication between all HCPs will help ensure that the most appropriate care is received*

Monitor and track any new signs or symptoms

Any new signs or symptoms developed should be reported to the oncology team

Prompt evaluation and management of symptoms are very important

Note that AEs can occur at any time after the start of therapy

Most AEs are mild to moderate in severity but are reversible if detected early and promptly addressed

# Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0

## GRADE 1

Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

## GRADE 2

Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living.

## GRADE 3

Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living.

## GRADE 4

Life-threatening consequences; urgent intervention indicated.

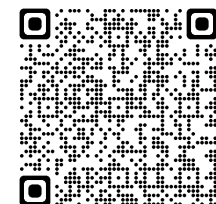
## GRADE 5

Death related to AE.

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.



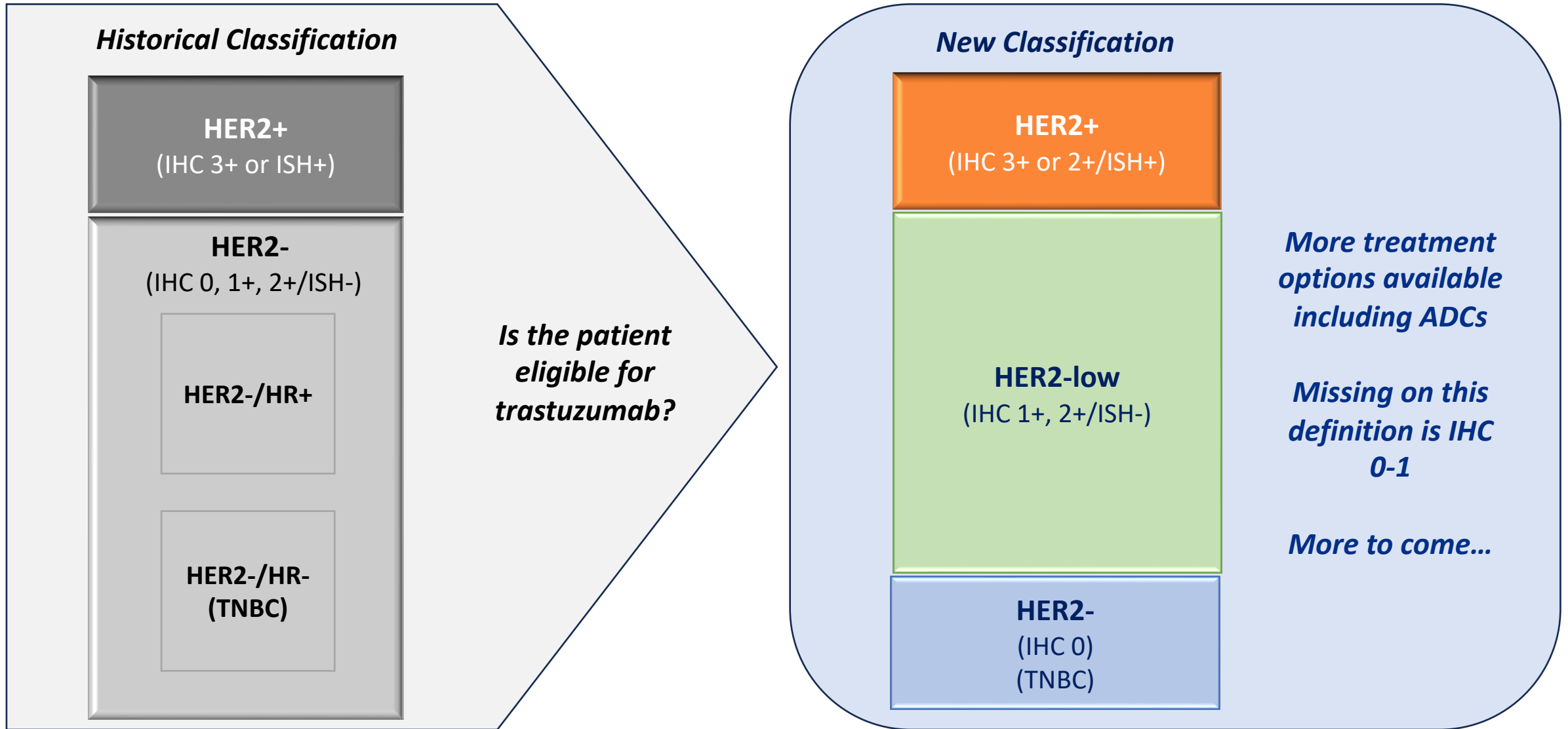
[Common Terminology Criteria for Adverse Events \(CTCAE\) \(cancer.gov\)](https://www.cancer.gov/ctcae)



# Antibody Drug Conjugates And Breast Cancer

Angela Brakhop, PhD

# HER2 Testing





# Breast Cancer: ADC Clinical Trials Comparison of HR+

	DESTINY-Breast03		DESTINY-Breast04		TROPiCS-02	
<b>Indication</b>	<i>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</i>		<i>Unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.</i>		<i>Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease</i>	
<b>Study Design</b>	<b>T-DXD vs T-DM1 (N=524)</b>		<b>T-DXd vs TPC (N=557)</b>		<b>Sacituzumab Govitecan vs TPC (N=543)</b>	
<b>Inclusion Criteria</b>	<ul style="list-style-type: none"> <li>Unresectable or metastatic HER2+ BC</li> <li><b>Previously treated with trastuzumab and a taxane</b> in advanced or metastatic setting</li> <li>Could have clinically stable, treated brain metastases</li> </ul>		<ul style="list-style-type: none"> <li>HER2-low (IHC 1+ or IHC 2+/ISH-) unresectable or metastatic BC</li> <li>≥1 ET if HR+</li> <li><b>1-2 lines of chemotherapy</b> in the metastatic setting or recurrence ≤6 mo after adjuvant CT</li> <li>Treated, stable brain metastases eligible</li> </ul>		<ul style="list-style-type: none"> <li>Metastatic or locally recurrent, inoperable HR+/HER2- breast cancer with disease progression</li> <li>At least 1 ET, taxane, and CDK4/6 inhibitor in any setting</li> <li><b>2-4 previous lines of CT</b> for metastatic disease (neo/adjuvant therapy qualified as a prior line of CT if disease recurred within 12 mo)</li> </ul>	
<b>N of HR+ pts</b>	131	134	331	163	272	271
<b>Median PFS, months</b>	<b>28.8</b>	6.8	<b>10.1</b>	5.4	<b>5.5</b>	4.0
<b>Median OS, months</b>	<b>Not reached</b>	Not reached	<b>23.9</b>	17.5	<b>13.9</b>	12.3
<b>ORR, %</b>	<b>78.5</b>	35.0	<b>52.6</b>	16.3	<b>21</b>	14
<b>Median DoR, months</b>	<b>36.6</b>	23.8	<b>10.7</b>	6.8	<b>7.4</b>	5.6



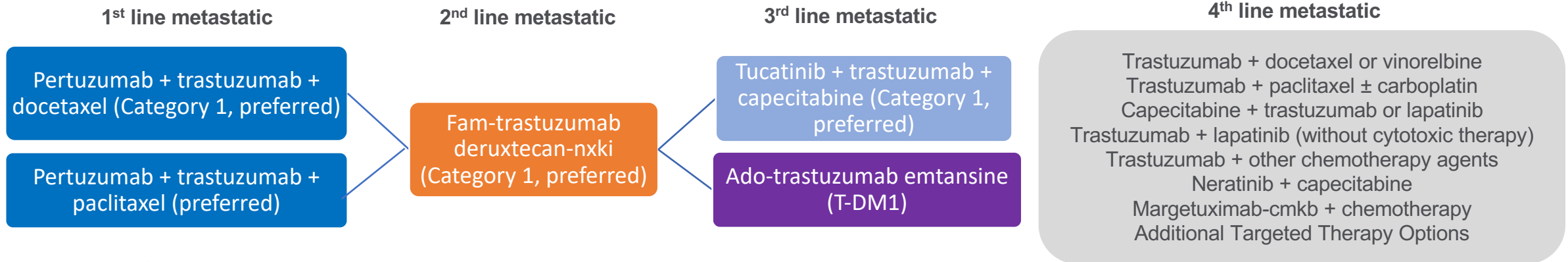
# HER2-positive metastatic Breast Cancer

SYSTEMIC THERAPY REGIMENS FOR RECURRENT UNRESECTABLE (LOCAL OR REGIONAL) OR STAGE IV (M1) DISEASE<sup>k</sup>

HR-Positive or -Negative and HER2-Positive <sup>l,k</sup>	
Setting	Regimen
First Line <sup>l</sup>	Pertuzumab + trastuzumab + docetaxel (Category 1, preferred)
	Pertuzumab + trastuzumab + paclitaxel (preferred)
Second Line <sup>n</sup>	Fam-trastuzumab deruxtecan-nxki <sup>m</sup> (Category 1, preferred)
Third Line	Tucatinib + trastuzumab + capecitabine <sup>n</sup> (Category 1, preferred)
	Ado-trastuzumab emtansine (T-DM1) <sup>o</sup>
Fourth Line and Beyond (optimal sequence is not known) <sup>p</sup>	Trastuzumab + docetaxel or vinorelbine
	Trastuzumab + paclitaxel ± carboplatin
	Capecitabine + trastuzumab or lapatinib
	Trastuzumab + lapatinib (without cytotoxic therapy)
	Trastuzumab + other chemotherapy agents <sup>q,r</sup>
	Neratinib + capecitabine
	Margetuximab-cmkb + chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine)
Additional Targeted Therapy Options <a href="#">see BINV-Q (6)</a>	

ADCs as treatment options for metastatic HER2-positive breast cancer:

- **Fam-trastuzumab deruxtecan-nxki (ENHERTU)**
- **Ado-trastuzumab emtansine (KADCYLA)**



# HR-positive, HER2-negative metastatic Breast Cancer



National  
Comprehensive  
Cancer  
Network®

**NCCN Guidelines Version 4.2023**  
**Invasive Breast Cancer**

[NCCN Guidelines Index](#)  
[Table of Contents](#)  
[Discussion](#)

ADCs as treatment options for metastatic HER2-negative breast cancer:

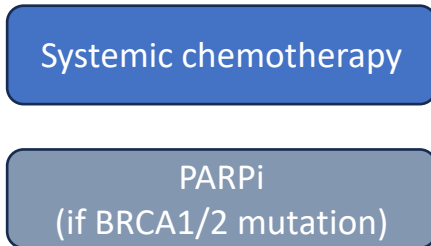
- **Fam-trastuzumab deruxtecan-nxki (ENHERTU)**
  - *HER2 IHC 1+ or 2+/ISH negative*
- **Sacituzumab govitecan (TRODELVY)**

**SYSTEMIC THERAPY REGIMENS FOR RECURRENT UNRESECTABLE (LOCAL OR REGIONAL) OR STAGE IV (M1) DISEASE<sup>a</sup>**

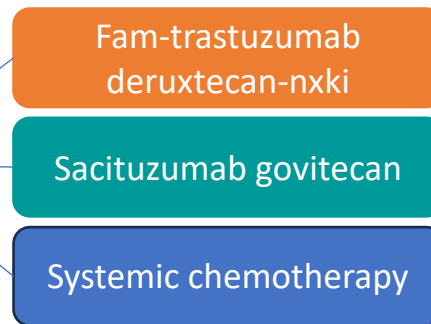
HR-Positive and HER2-Negative with Visceral Crisis <sup>†</sup> or Endocrine Refractory		
Setting	Subtype/Biomarker	Regimen
First Line	No germline <i>BRCA1/2</i> mutation <sup>b</sup>	Systemic chemotherapy <a href="#">see BINV-Q (5)</a>
	Germline <i>BRCA1/2</i> mutation <sup>b</sup>	PARPi (olaparib, talazoparib) <sup>c</sup> (Category 1, preferred)
Second Line	HER2 IHC 1+ or 2+/ISH negative <sup>d</sup>	Fam-trastuzumab deruxtecan-nxki <sup>e</sup> (Category 1, preferred)
	Not a candidate for fam-trastuzumab deruxtecan-nxki	Sacituzumab govitecan <sup>f</sup> (Category 1, preferred) Systemic chemotherapy <a href="#">see BINV-Q (5)</a>
Third Line and beyond	Any	Systemic chemotherapy <a href="#">see BINV-Q (5)</a>
	Biomarker positive (ie, MSI-H, NTRK, RET, TMB-H)	Targeted agents <a href="#">see BINV-Q (6)</a>

<sup>†</sup> According to the 5th ESO-ESMO international consensus guidelines (Cardoso F, et al. Ann Oncol 2020;31:1625) for advanced breast cancer visceral crisis is defined as: "severe organ dysfunction, as assessed by signs and symptoms, laboratory studies and rapid progression of disease. Visceral crisis is not the mere presence of visceral metastases but implies important organ compromise leading to a clinical indication for the most rapidly efficacious therapy."

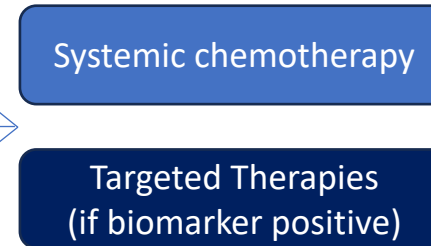
**1<sup>st</sup> line metastatic**



**2<sup>nd</sup> line metastatic**



**3<sup>rd</sup> line metastatic**



\*updated from presented deck



# HR-negative, HER2-negative metastatic Breast Cancer



National  
Comprehensive  
Cancer  
Network®

**NCCN Guidelines Version 4.2023**  
**Invasive Breast Cancer**

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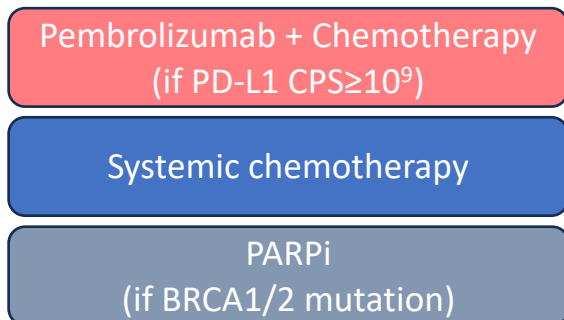
ADCs as treatment options for metastatic HER2-negative breast cancer:

- **Fam-trastuzumab deruxtecan-nxki (ENHERTU)**
  - *HER2 IHC 1+ or 2+/ISH negative*
- **Sacituzumab govitecan (TRODELVY)**

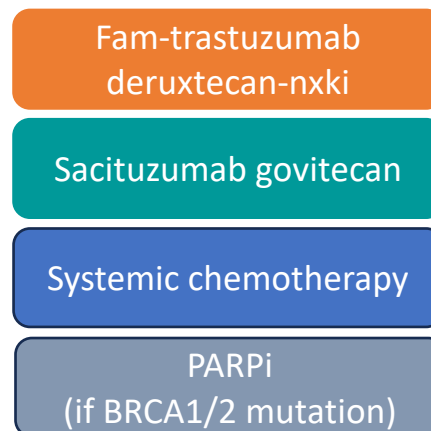
## SYSTEMIC THERAPY REGIMENS FOR RECURRENT UNRESECTABLE (LOCAL OR REGIONAL) OR STAGE IV (M1) DISEASE<sup>a</sup>

HR-Negative and HER2-Negative (Triple-Negative Breast Cancer; TNBC)		
Setting	Subtype/Biomarker	Regimen
<b>First Line</b>	PD-L1 CPS $\geq 10^9$ regardless of germline <i>BRCA</i> mutation status <sup>b</sup>	Pembrolizumab + chemotherapy (albumin-bound paclitaxel, paclitaxel, or gemcitabine and carboplatin) <sup>h</sup> (Category 1, preferred)
	PD-L1 CPS $< 10^9$ and no germline <i>BRCA1/2</i> mutation <sup>b</sup>	Systemic chemotherapy <a href="#">see BINV-Q (5)</a>
	PD-L1 CPS $< 10^9$ and germline <i>BRCA1/2</i> mutation <sup>b</sup>	<ul style="list-style-type: none"> <li>• PARPi (olaparib, talazoparib) (Category 1, preferred)</li> <li>• Platinum (cisplatin or carboplatin) (Category 1, preferred)</li> </ul>
<b>Second Line</b>	Germline <i>BRCA1/2</i> mutation <sup>b</sup>	PARPi (olaparib, talazoparib) (Category 1, preferred)
	Any	Sacituzumab govitecan <sup>i</sup> (Category 1, preferred) Systemic chemotherapy <a href="#">see BINV-Q (5)</a>
	No germline <i>BRCA1/2</i> mutation <sup>b</sup> and HER2 IHC 1+ or 2+/ISH negative <sup>d</sup>	Fam-trastuzumab deruxtecan-nxki <sup>e</sup> (Category 1, preferred)
<b>Third Line and beyond</b>	Biomarker positive (ie, MSI-H, NTRK, RET, TMB-H)	Targeted agents <a href="#">see BINV-Q (6)</a>
	Any	Systemic chemotherapy <a href="#">see BINV-Q (5)</a>

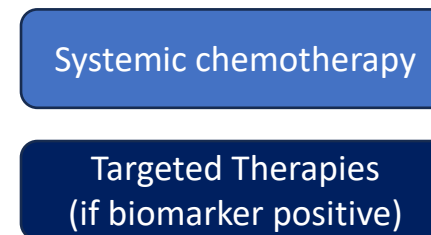
### 1<sup>st</sup> line metastatic



### 2<sup>nd</sup> line metastatic



### 3<sup>rd</sup> line metastatic and beyond





# **HR+ Breast Cancer Patient Case Study**

*Katie Alexander*



**37 year old female, HR+ Breast Cancer**

**History:** *Pt was originally diagnosed while living in a South American Country. PMH is negative; PSH is positive for c-sections x3 and b/l breast augmentation in 2013; presents on no home medications.*

## **Diagnostic information**

- **Aug 2018:** Pt self-palpated a left breast mass. Underwent left breast partial mastectomy plus axillary lymph node dissection. Pathology returned at 1.5 cm invasive ductal carcinoma; grade 3. Six (6) lymphatic nodes and two (2) lymph node conglomerate were found, all positive for metastatic disease.
  - Staged at pT1cN3Mx
  - ER + 20%; PR + 50%; **HER2/neu negative.**
- **Feb 2019:** NGS showed no TMB; PD-L1 negative; **HER2/neu 3+** and androgen receptor of 3+.



## 37 year old female, HR+ Breast Cancer

### Aug 2018:

Received 4 cycles of **cisplatin plus paclitaxel** followed by 2 cycles **doxorubicin plus cyclophosphamide**.

### Nov 2018:

Clinical recurrence in the left axillary region.

Surgical resection showed HER2 IHC 3+.

Received **trastuzumab plus RT**.

### Feb 2019:

Tolerated 2 cycles of **taxotere, cytoxan and Herceptin (TCH)** but did not proceed, reasoning unknown.

Maintained on oral adjuvant **capecitabine** for six cycles until Oct of 2019.

Received **bicalutamide** in Oct 2019 (off label use).

### Sept 2020:

Recurrent malignancy.

Received **docetaxel, pertuzumab and trastuzumab**.

Worsening anasarca and left pleural effusion. Thoracentesis was complete but negative for malignancy.

### May 2021:

Progression: brain metastases.

Underwent whole brain radiation; received **lapatinib plus trastuzumab and pertuzumab**; developed grade 2/3 diarrhea.

Last cycle of trastuzumab and pertuzumab late June 2021; moved to the US in July 2021.

### Aug 2021:

Progression: bone lesions

Started on **ado-trastuzumab/TDM-1 (Kadcyla)**.

### Jan 2022:

Increased brain lesions, underwent **cyberknife**, continued **TDM-1**.



## 37 year old female, HR+ Breast Cancer

### August 2021:

Progression: bone lesions

Pt was started on **ado-trastuzumab/ TDM-1 (Kadcyla)**

**Jan 2022:** Increased brain lesions, underwent **cyberknife** and continued **TDM-1**.

### July 2022:

MRI brain shows increased in right frontal lesion; confirmed activity in T5

Received **fam-trastuzumab deruxtecan/T-DXd (Enhertu)**.

Developed grade 3 neutropenia prior to cycles 3 and 4, which lead to treatment delays.

### October 2022:

MRI of the brain shows excellent response with significant improvement.

### April 2023:

CT C/A/P shows continued stable disease

### May 2023:

MRI brain shows minor increase in left cerebellar lesion; plan to continue to on therapy with **Enhertu**.





# **HR-, HER2- Breast Cancer Patient Case Study**

*Katie Alexander*



**63 year old male**

**History:** *PMH of CVA; HTN; hyperlipidemia; DM; SCC and Basal cell of the skin and syring in the thoracic spine. PSH is significant for basal cell and SCC removed from skin and brain aneurysm stent. Pt is also noted to carry the MTRF mutation. Family history is significant for five sisters all with hypertension, high cholesterol. One sister with breast cancer, and one sister with melanoma. Pt had a stroke in October 2008 which lead to dysphagia. Prior to his CVA, he did have a breast biopsy for a mass in his breast that returned with atypical cells only, no concerns for malignancy.*

### **Diagnostic information**

**July 2017:** Pt reports pain for a year and half. Ultrasound showed left axilla mass. CT scan of the chest showed axillary adenopathy with extension into the pectoral muscles; lytic lesions in the left scapula and questionable abnormalities in left adrenal gland. Fine needle biopsy of left axillary node consistent with breast primary tissue. Pathology shows ***ER/PR (-); Her2/neu (-) with a Ki-67 of 80%***. Staged at pT1cN3Mx.



## 63 year old male, treatment history

### July 2017:

Received weekly **Taxol** with some improvement in metastasis.

Taxol was held and pt underwent **radiation therapy** for pain control.

Received a total of 15 cycles of chemo.

### October 2017- October 2020:

Decision to hold on treatment initiation and continue to monitor.

Scans every 3 months show minimal progression.

### November 2020:

NGS shows high tumor mutation burden.

Started on **pembrolizumab (Keytruda)**.

Scans remained stable until July 2021.

### July 2021:

CT scan shows progression.

**Keytruda** was stopped.

Received **palliative radiation** for pain control.

Completed 10 treatments XRT.

### July 2021-April 2022:

Stable scans.

### April 2022:

Progression with significant destruction of bone.

Started on **sacituzumab govitecan (Trodelvy)**.

Remains on **Trodelvy** with stable scans and tolerable pain regimen.