#### SELECTED SAFETY INFORMATION

#### **BOXED WARNINGS**

### Cardiomyopathy

- Administration of trastuzumab products can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens
- Evaluate left ventricular function in all patients prior to and during treatment with TRAZIMERA. Discontinue TRAZIMERA treatment in patients receiving adjuvant therapy and withhold TRAZIMERA in patients with metastatic disease for clinically significant decrease in left ventricular function

### Infusion Reactions; Pulmonary Toxicity

 Administration of trastuzumab products can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt TRAZIMERA infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue TRAZIMERA for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome

## **Embryo-Fetal Toxicity**

 Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception



FDA-approved biosimilars such as trastuzumab-qyyp (TRAZIMERA®) are recommended as appropriate substitutes for trastuzumab in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)1-3\*+1

Trazimera<sup>®</sup> trastuzumab-qyyp **Pfizer** 

# A PFIZER BIOSIMILAR **BUILT ON EXPERIENCE**

Part of the largest oncology biosimilars portfolio<sup>4</sup>



TRAZIMERA product and reimbursement information for your practice

Indications	>	Pfizer Oncology Together™	>
Payer Coverage by Region	>	Important Safety Information	>
Ordering	>	References	>
Learn n	nore about	t TRAZIMERA	

<sup>\*</sup>Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar and the reference product.

<sup>†</sup>NCCN Guidelines® recommend the use of an FDA-approved biosimilar as an appropriate substitute for trastuzumab. See the NCCN Guidelines for detailed recommendations, including specific treatment regimens. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

# TRAZIMERA® (trastuzumab-qyyp) Is FDA Approved Across All Indications of Herceptin® (trastuzumab)<sup>3</sup>

#### **INDICATIONS**

**Pfizer** 

Trazimera<sup>®</sup>

trastuzumab-qyyp



### **Adjuvant Breast Cancer**

For adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature\*) breast cancer:

- As part of a treatment regimen containing doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- As part of a treatment regimen with docetaxel and carboplatin
- As a single agent following multimodality anthracycline-based therapy

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.



#### **Metastatic Breast Cancer**

- In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

ER=estrogen receptor; HER=human epidermal growth factor receptor; PR=progesterone receptor.

### SELECTED SAFETY INFORMATION

# Cardiomyopathy

- Administration of trastuzumab products can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens. In a pivotal adjuvant breast cancer trial, one patient who developed CHF died of cardiomyopathy
- Trastuzumab products can cause left ventricular cardiac dysfunction, arrhythmias, hypertension, disabling cardiac failure, cardiomyopathy, and cardiac death

(continued on next page)

<sup>\*</sup>High risk is defined as ER/PR positive with one of the following features: pathological tumor size > 2 cm, tumor grade 2 to 3, or age < 35 years.

3

# TRAZIMERA® (trastuzumab-qyyp) Is FDA Approved Across All Indications of Herceptin® (trastuzumab)³





#### **Metastatic Gastric Cancer**

• In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

## **SELECTED SAFETY INFORMATION**

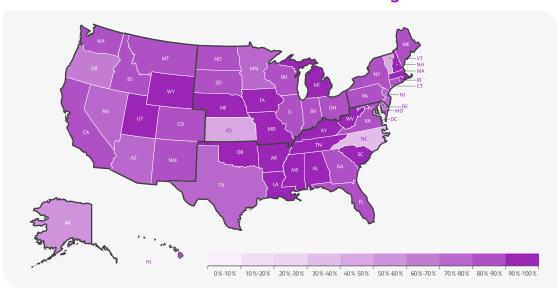
Cardiomyopathy (continued)

- Trastuzumab products can also cause asymptomatic decline in LVEF
- Discontinue TRAZIMERA treatment in patients receiving adjuvant breast cancer therapy and withhold TRAZIMERA in patients with metastatic disease for clinically significant decrease in left ventricular function

# National and State Coverage Rates<sup>5</sup>

Individual state rates represent the percentage of commercial lives where TRAZIMERA® (trastuzumab-qyyp) is covered at parity or at an advantage to Herceptin® (trastuzumab)\*+

# Click on a region to learn more



# National access rates at **parity** or **better**, compared to Herceptin



93%
of Medicare lives covered nationwide, including managed Medicare\*\*

<sup>†</sup>The information provided in this communication is not a guarantee of coverage or payment (partial or full). Actual benefits are determined by each plan administrator in accordance with its respective policy and procedures. Nothing herein may be construed as an endorsement, approval, recommendation, representation, or warranty of any kind by any plan or insurer.

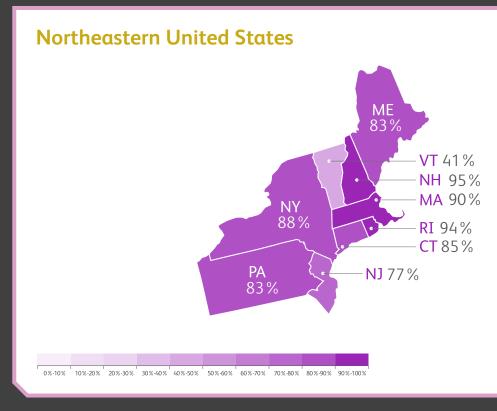
# **SELECTED SAFETY INFORMATION**

### **Cardiac Monitoring**

- Evaluate cardiac function prior to and during treatment. For adjuvant breast cancer therapy, also evaluate cardiac function after completion of TRAZIMERA
- Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan
- Monitor frequently for decreased left ventricular function during and after TRAZIMERA treatment
- Monitor more frequently if TRAZIMERA is withheld for significant left ventricular cardiac dysfunction

<sup>\*</sup>As of April 2022.





Individual state rates represent the percentage of commercial lives where TRAZIMERA® (trastuzumab-qyyp) is covered at parity or at an advantage to Herceptin® (trastuzumab)\*†

\*As of April 2022.

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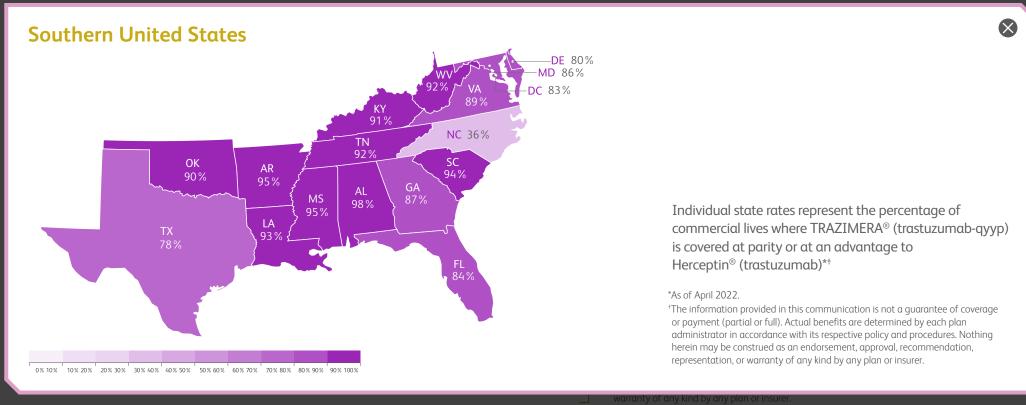
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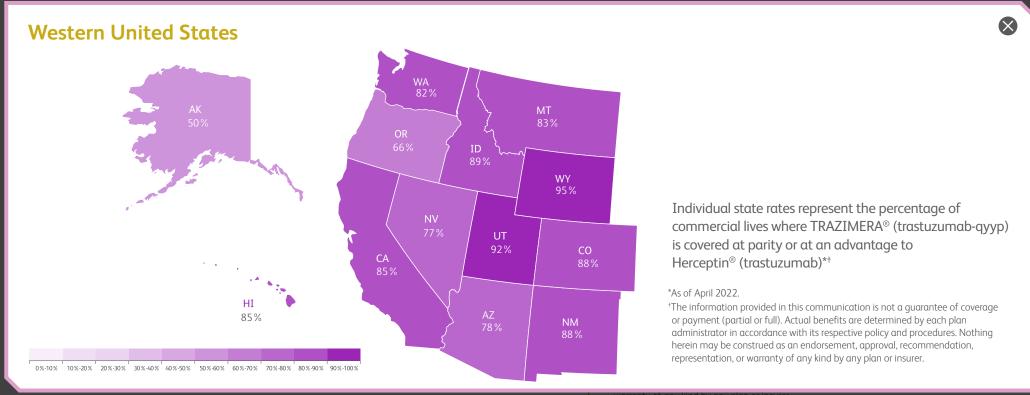


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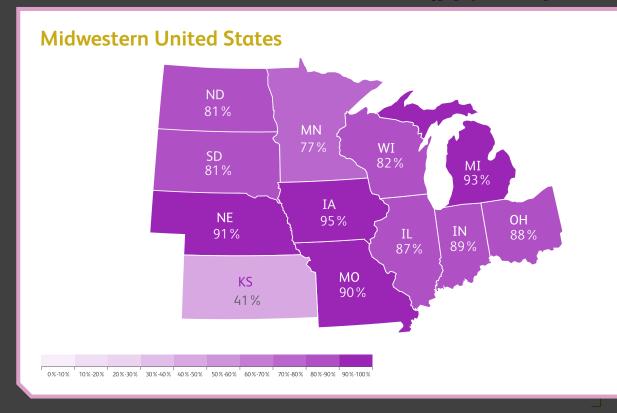


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Individual state rates represent the percentage of commercial lives where TRAZIMERA® (trastuzumab-qyyp) is covered at parity or at an advantage to Herceptin® (trastuzumab)\*†

\*As of April 2022.

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# An FDA-Approved Biosimilar to Herceptin® (trastuzumab)<sup>3</sup>

TRAZIMERA is available in single- and multiple-dose options<sup>3</sup>

Ordering TRAZIMERA—What You Need to Know <sup>3,5-7</sup>				
Unit of Sale	150 mg SDV	420 mg MDV*		
Unit of Sale NDC	0069-0308-01	0069-0305-01		
Unit of Sale Quantity	1 vial per carton	1 vial per carton		
Unit of Sale List Price†	\$1,211.10	\$3,391.08		
HCPCS Code	Q5116			
OPPS Status	G: Pass-through payment			

MDV=multiple-dose vial; OPPS=Outpatient Prospective Payment System; SDV=single-dose vial.

\*For multiple-dose vial, unused product can be stored for future use. Store reconstituted TRAZIMERA MDV in the refrigerator at 2 to 8 °C (36 to 46 °F); discard unused TRAZIMERA after 28 days. If TRAZIMERA is reconstituted with Sterile Water for Injection without preservative, use immediately and discard any unused portion. Do not freeze. †As of May 2022.

### **SELECTED SAFETY INFORMATION**

#### **Infusion Reactions**

- Administration of trastuzumab products can result in serious and fatal infusion reactions
- Symptoms usually occur during or within 24 hours of administration of trastuzumab products
- Interrupt TRAZIMERA infusion for dyspnea or clinically significant hypotension
- Monitor patients until symptoms completely resolve
- Discontinue TRAZIMERA for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Strongly consider permanent discontinuation in all patients with severe infusion reactions
- Infusion reactions consist of a symptom complex characterized by fever and chills, and on occasion include nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, dyspnea, hypotension, rash, and asthenia

Pfizer Oncology **Together** ™

References

# **Pfizer Oncology** together<sup>™</sup>

# Making your patients' support needs a priority. Together.

Pfizer Oncology Together $^{\mathrm{m}}$  is a personalized support program to help patients and their loved ones throughout TRAZIMERA treatment. We can assist with the access and reimbursement process and help identify financial assistance options for your patients prescribed TRAZIMERA. And when your patients need support for their day-to-day challenges, we can provide them with a dedicated Care Champion who has social work experience and can connect them to resources that may help. Because when it comes to support, we're in this together.



FOR LIVE, PERSONALIZED SUPPORT Call 1-877-744-5675 (Monday-Friday 8 AM-8 PM ET)

**VISIT** PfizerOncologyTogether.com

## SELECTED SAFETY INFORMATION

### **Embryo-Fetal Toxicity**

- Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception
- Verify the pregnancy status of females of reproductive potential prior to the initiation of TRAZIMERA
- Advise pregnant women and females of reproductive potential that exposure to TRAZIMERA during pregnancy or within 7 months prior to conception can result in fetal harm
- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of TRAZIMERA
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for TRAZIMERA treatment and any potential adverse effects on the breastfed child from TRAZIMERA or from the underlying maternal condition

# Important Safety Information and Indications

# BOXED WARNINGS AND ADDITIONAL IMPORTANT SAFETY INFORMATION Cardiomyopathy

- Administration of trastuzumab products can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens
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# Trazimera® trastuzumab-qyyp

# Important Safety Information and Indications (continued)

### **Cardiac Monitoring**

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**Important** Safety Information

References

# Important Safety Information and Indications (continued)

### **Pulmonary Toxicity**

- Administration of trastuzumab products can result in serious and fatal pulmonary toxicity, which includes dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, noncardiogenic pulmonary edema, pulmonary insufficiency and hypoxia, acute respiratory distress syndrome, and pulmonary fibrosis. Such events can occur as sequelae of infusion reactions
- Patients with symptomatic intrinsic lung disease or with extensive tumor involvement of the lungs, resulting in dyspnea at rest, appear to have more severe toxicity
- Discontinue TRAZIMERA in patients experiencing pulmonary toxicity

### Exacerbation of Chemotherapy-Induced Neutropenia

• In randomized, controlled clinical trials, the numbers of per-patient incidences of NCI-CTC Grade 3-4 neutropenia and of febrile neutropenia were higher in patients receiving trastuzumab in combination with myelosuppressive chemotherapy as compared to those who received chemotherapy alone The incidence of septic death was similar among patients who received trastuzumab and those who did not

#### **Most Common Adverse Reactions**

- The most common adverse reactions associated with trastuzumab products in breast cancer were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatique, dyspnea, rash, neutropenia, anemia, and myalgia
- The most common adverse reactions associated with trastuzumab products in metastatic gastric cancer were neutropenia, diarrhea, fatique, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia

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Ordering

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References

# Important Safety Information and Indications (continued)

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#### **INDICATIONS**

### **Adjuvant Breast Cancer**

TRAZIMERA is indicated for adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR negative or with one high risk feature\*) breast cancer:

- As part of a treatment regimen containing doxorubicin, cyclophosphamide and either paclitaxel or docetaxel
- As part of a treatment regimen with docetaxel and carboplatin
- As a single agent following multi-modality anthracycline based therapy

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

\*High risk is defined as ER/PR positive with one of the following features: tumor size > 2 cm, age < 35 years, or tumor grade 2 or 3.

#### **Metastatic Breast Cancer**

TRAZIMERA is indicated:

- In combination with paclitaxel for the first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

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TRAZIMERA is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

References

# References

- 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.2.2021. © 2021 National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the guideline, go online to NCCN.org.
- 2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer V.2.2022. © 2022 National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the guideline, go online to NCCN.org.
- 3. TRAZIMERA [prescribing information]. New York, NY: Pfizer Inc.; November 2020.
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TRAZIMERA is a registered trademark of Pfizer Inc. Herceptin® (trastuzumab) is a registered trademark of Genentech, Inc.

Please see Important Safety Information and Indications on pages 7-10 and full Prescribing Information, including BOXED WARNINGS, available at TrazimeraHCP.com.

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