An FDA-approved biosimilar to Herceptin® (trastuzumab)[1]*

TRAZIMERA® (trastuzumab-qyyp) product and reimbursement information for your practice

TRAZIMERA Injection for Intravenous Use

Ordering TRAZIMERA—What You Need to Know[1,2]		
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[3]	**Descriptor**	
Q5116	Injection, trastuzumab-qyyp, biosimilar, (TRAZIMERA), 10 mg	

MDV=multiple-dose vial; SDV=single-dose vial.

*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.[1]

†As of February 2020.

The Centers for Medicare & Medicaid Services (CMS) assigned TRAZIMERA an Outpatient Prospective Payment System (OPPS) pass-through indicator status of G[3]

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**
- **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**

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Please see Important Safety Information and Indications throughout and full Prescribing Information, including BOXED WARNINGS, available at TrazimeraHCP.com.

INJECTION
Trazimera®
trastuzumab-qyyp
Pfizer

BOXED WARNINGS AND ADDITIONAL IMPORTANT SAFETY INFORMATION (CONTINUED)

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**

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
- 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**

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

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BOXED WARNINGS AND ADDITIONAL IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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

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

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BOXED WARNINGS AND ADDITIONAL IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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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

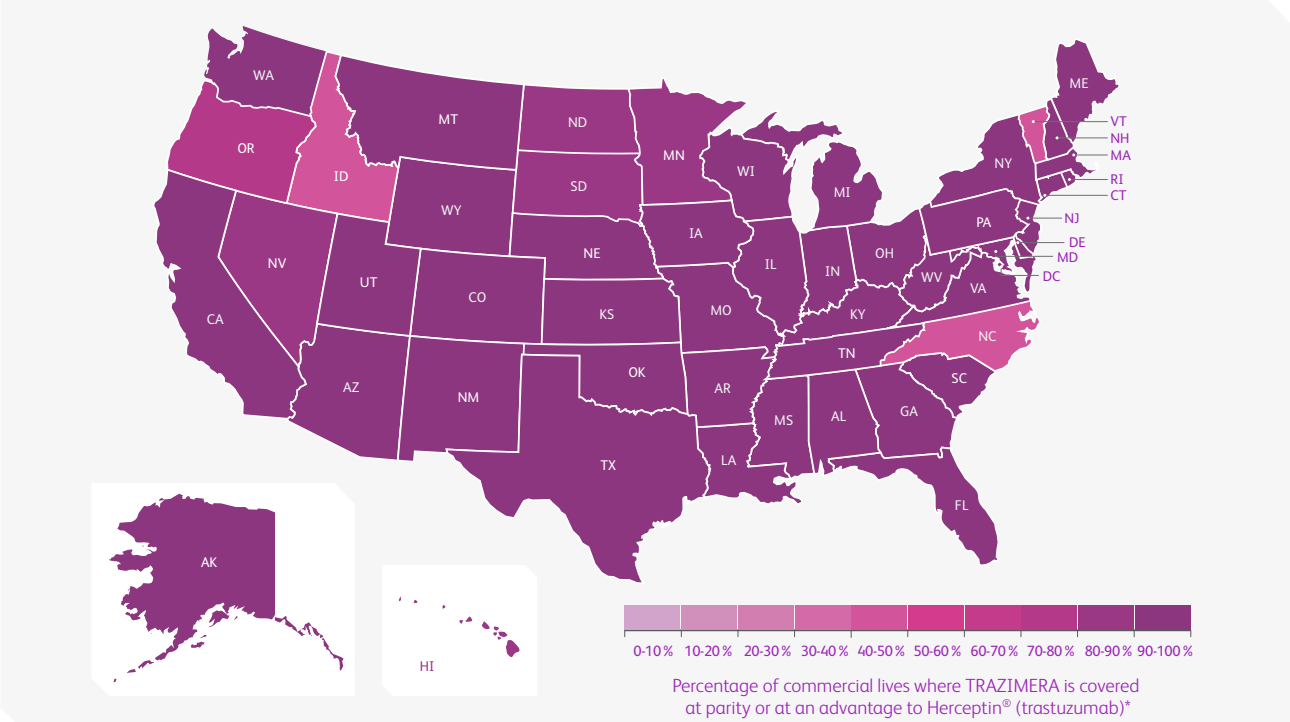
Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Metastatic Gastric Cancer

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.

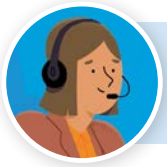
TRAZIMERA Payer Coverage Nationwide



93%
of Medicare lives covered, including managed Medicare[2*†]

94%
of commercially insured patients have access to TRAZIMERA nationwide[2*†]

*As of September 2021.
†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.



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

VISIT
PfizerOncologyTogether.com

References: 1. TRAZIMERA [prescribing information]. New York, NY: Pfizer Inc.; November 2020. **2.** Data on file. Pfizer Inc., New York, NY. **3.** Centers for Medicare & Medicaid Services. July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS). Updated July 1, 2020.

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