Pfizer Oncology together™

INJECTION
Trazimera®
trastuzumab-qyyp
Pfizer

TRAZIMERA® Billing and Coding Guide

Please see Important Safety Information and Indications on pages 11-12 and full Prescribing Information for TRAZIMERA, including BOXED WARNINGS, at TRAZIMERAhcp.com.

Introduction

Pfizer Inc. has developed this reference guide to assist healthcare providers (HCPs) with understanding coding for TRAZIMERA (trastuzumab-qyyp), a trastuzumab biosimilar approved for use in the United States for intravenous use.

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for TRAZIMERA. Coding and coverage policies change periodically and often without notice. The HCP is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for TRAZIMERA.

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Making your patients' support needs a priority. Together.

At Pfizer Oncology Together, patient support is at the core of everything we do. We've gathered resources and developed tools to help patients and their loved ones throughout TRAZIMERA treatment. From helping to identify financial assistance options to connecting patients to resources for emotional support, your patients' needs are our priority.*

Benefits Verification

We can help determine a patient's coverage and out-of-pocket costs.

Prior Authorization (PA) Assistance

We can coordinate with a patient's insurer to determine the PA requirements. After a PA request is submitted, we can follow up with the payer until a final outcome is determined.

Appeals Assistance

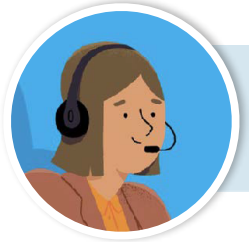
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

Billing and Coding Assistance for Injectable Products

For your patient claim submissions, we provide easy access to sample forms and template letters, along with billing and coding information for physician office and hospital outpatient settings of care.

Patient Financial Assistance

We can help patients understand their benefits and connect them with financial assistance resources.



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

VISIT
PfizerOncologyTogether.com

*Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

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Coding for TRAZIMERA

In the physician office and hospital outpatient department sites of care, Medicare, Medicaid, and private commercial payers typically recognize the following codes for reporting TRAZIMERA and its administration on claim forms.

Effective for dates of service on and after October 1, 2019, HCPCS code Q5116 may be used to report TRAZIMERA.

HCPCS Code[1]	*Descriptor*
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg

Modifiers may be included on claims to provide additional information. Some payers may require modifier JA to be reported, indicating an intravenous route of administration. For the TRAZIMERA single-dose vial (SDV), the JW modifier is used to report the amount of drug that is unused after administration to a patient. For Medicare and some payers, the unused amount should be reported on a separate line of the claim form, and the claim should include the drug code, modifier, and number of units discarded.[2] Additional modifiers may also be considered appropriate when submitting claims.

HCPCS Modifier[3]	*Descriptor*
JA	Intravenous administration
JW*	Drug amount discarded/not administered to any patient

*Applicable to SDVs only.

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TRAZIMERA National Drug Code

National Drug Codes (NDCs) are unique 10-digit, 3-segment numbers used to identify drugs.[4]

Strength[5]	Vial Size	10-Digit NDC
420 mg/vial	420 mg lyophilized powder in a multiple-dose vial for reconstitution	0069-0305-01
150 mg/vial	150 mg lyophilized powder in a single-dose vial for reconstitution	0069-0308-01

NDC Conversion Example

For reimbursement purposes, some payers may require the HCP to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a "0" (zero) where appropriate to create a 5-4-2 configuration. The zero is added in front of the first segment of numbers when the 10-digit format is the 4-4-2 configuration. See placement of the red zero in the example below.

Strength	Vial Size	10-Digit NDC	11-Digit NDC
420 mg/vial	420 mg lyophilized powder in a multiple-dose vial for reconstitution	0069-0305-01	00069-0305-01
150 mg/vial	150 mg lyophilized powder in a single-dose vial for reconstitution	0069-0308-01	00069-0308-01

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Coding for TRAZIMERA Administration Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians.[6]
The following codes may be used to report the administration of TRAZIMERA:

Type of Code	*Code/Descriptor*	*Relevant Sites of Service*
Administration: CPT® codes[6]	**96413:** Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug	Physician office and hospital outpatient department
	96415: Chemotherapy administration, IV infusion technique; each additional hour (List separately in addition to code for primary procedure)	
	96417: Chemotherapy administration, IV infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)	

Hospital outpatient departments use revenue codes to report specific accommodations and/or ancillary charges.[7]

Type of Code	*Code/Descriptor*	*Relevant Sites of Service*
Revenue codes[8]	**0636:** Drugs requiring specific identification – detailed coding	Hospital outpatient department
	0500: Outpatient services – general classification	
	0510: Clinic – general classification	

Key: IV – intravenous
Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

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Diagnosis Coding for TRAZIMERA

TRAZIMERA (trastuzumab-qyyp) is an FDA-approved biosimilar.

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, as appropriate, to report the patient-specific diagnosis.

Reporting the medical necessity for TRAZIMERA may require a primary as well as secondary diagnosis, in some cases. HCPs should verify payer-specific coding requirements before submitting a claim and the order of required codes (eg, primary, secondary, etc), as these may vary by payer. ICD-10-CM codes may include, but are not limited to, the codes listed below:

ICD-10-CM Code[9]	*Descriptor*
C50.011—C50.019, C50.111—C50.119, C50.211—C50.219, C50.311—C50.319, C50.411—C50.419, C50.511—C50.519, C50.611—C50.619, C50.811—C50.819, C50.911—C50.919	Malignant neoplasm of breast (female)
C50.021—C50.029, C50.121—C50.129, C50.221—C50.229, C50.321—C50.329, C50.421—C50.429, C50.521—C50.529, C50.621—C50.629, C50.821—C50.829, C50.921—C50.929	Malignant neoplasm of breast (male)
C16.0—C16.9	Malignant neoplasm of stomach
Z17.0—Z17.1	Estrogen receptor status

TRAZIMERA Billing Units

The TRAZIMERA HCPCS code Q5116 is described as "Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg."

10 milligrams = 1 billing unit

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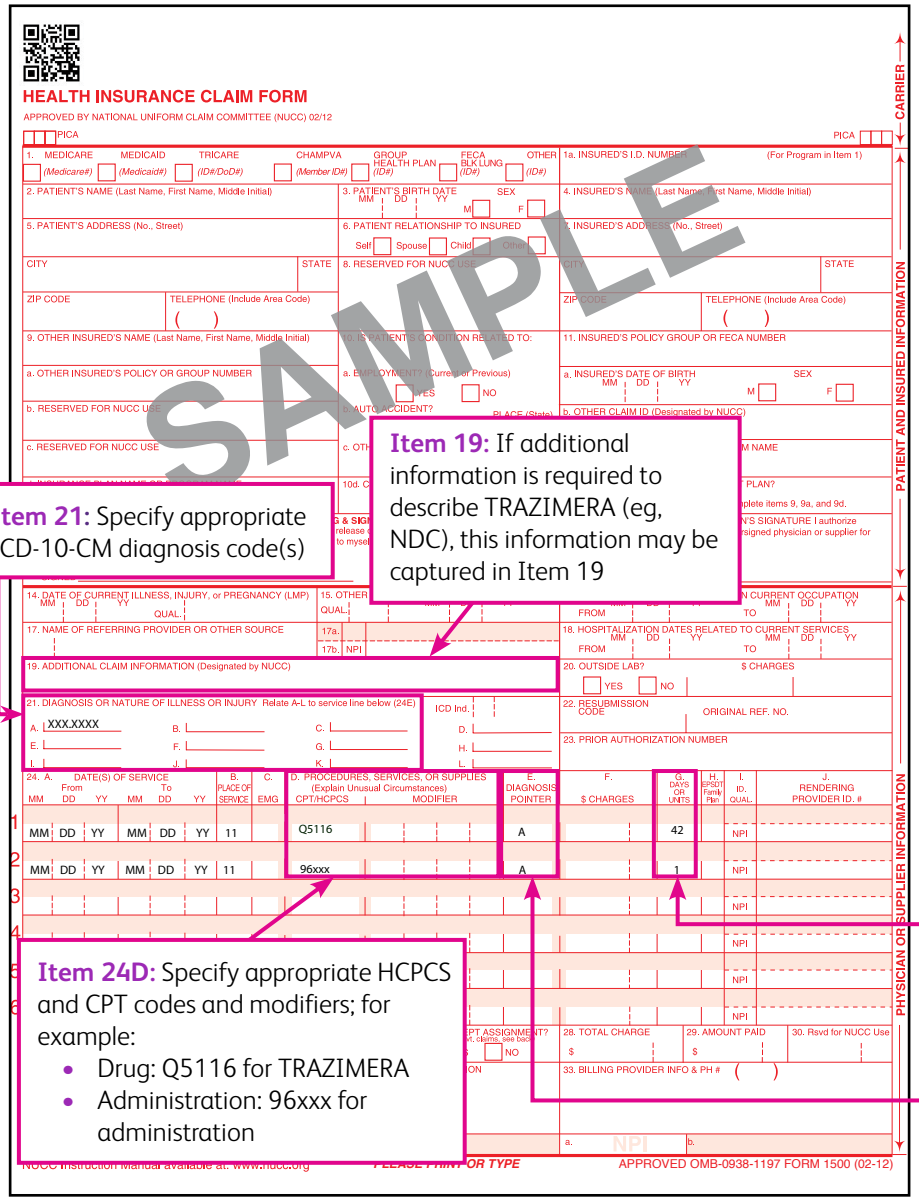
Sample Claim Form: CMS-1500, Physician Office Site of Service



This sample form is intended as a reference for the coding and billing of TRAZIMERA. This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

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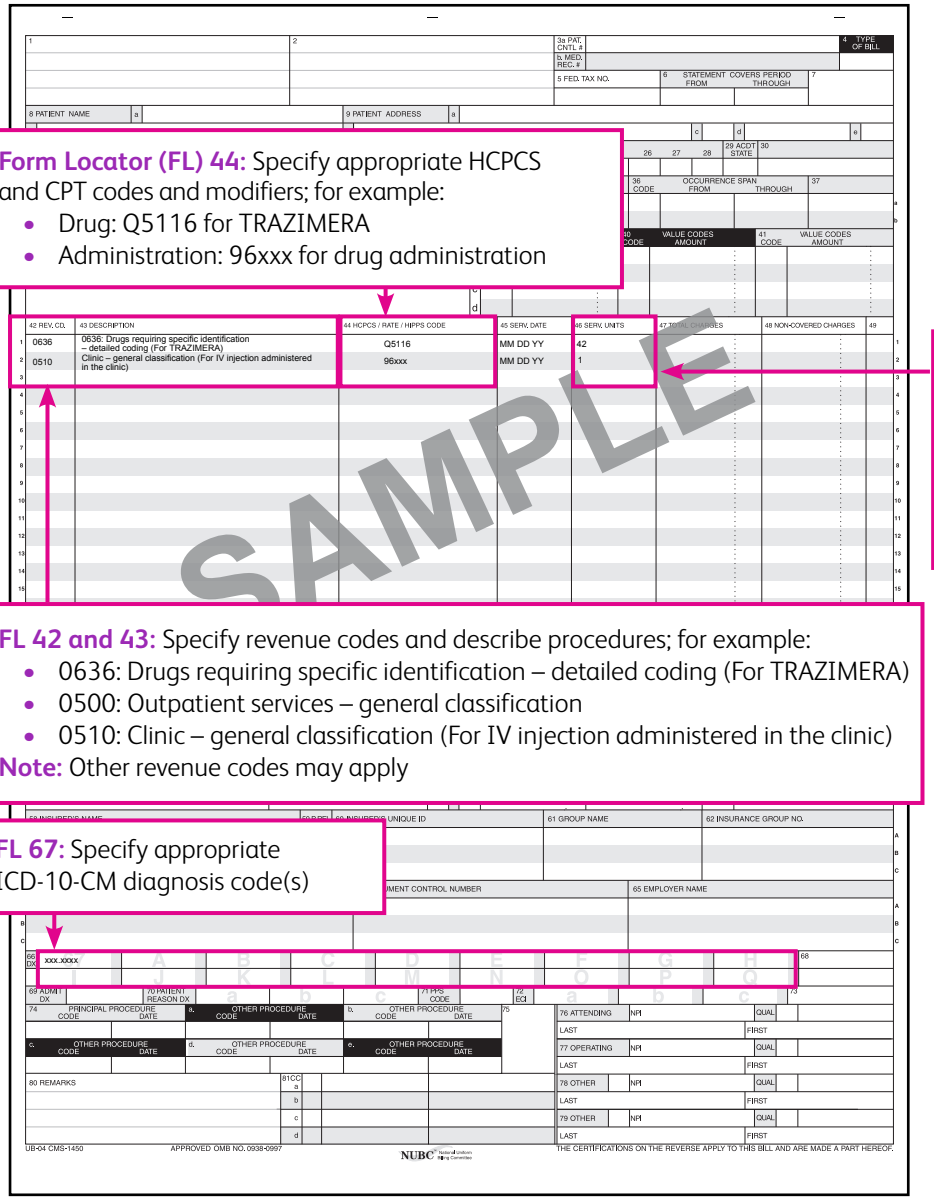
Sample Claim Form: UB-04, Hospital Outpatient Site of Service



Form Locator (FL) 44: Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5116 for TRAZIMERA
- Administration: 96xxx for drug administration

FL 46: Specify the billing units. For example, 1 billing unit = **10** mg of trastuzumab-qyyp biosimilar (TRAZIMERA) for HCPCS code Q5116. To bill 1 96xxx for drug administration, enter 1 billing unit

FL 42 and 43: Specify revenue codes and describe procedures; for example:

- 0636: Drugs requiring specific identification – detailed coding (For TRAZIMERA)
- 0500: Outpatient services – general classification
- 0510: Clinic – general classification (For IV injection administered in the clinic)

Note: Other revenue codes may apply

FL 67: Specify appropriate ICD-10-CM diagnosis code(s)

This sample form is intended as a reference for the coding and billing of TRAZIMERA. This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

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Claims Submission Checklist

The following may be considered to assist with submitting claims completely and accurately, which is important for timely claims processing, for appropriate payment, and to avoid denied claims.

- ☑ **Provide the patient name, address, and insurance identification number, and review these for accuracy**
- ☑ **Include the HCP's name, National Provider Identifier (NPI), and payer-specific provider ID (if applicable)**
- ☑ **Indicate the appropriate place of service code (2-digit code) for where the treatment was provided**
- ☑ **Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers (if applicable) are consistent with information included in the patient's medical record**
- ☑ **Review the TRAZIMERA-specific information (eg, name of drug, HCPCS code, NDC, number of units, route, and frequency of administration)**

References

1. Centers for Medicare & Medicaid Services (CMS). HCPCS Quarterly Update. January 2021 Alpha-Numeric HCPCS File. https://www.cms.gov/files/zip/january-2021-alpha-numeric-hcpcs-file.zip. Accessed December 7, 2020.
2. Centers for Medicare & Medicaid Services (CMS). Medicare program JW modifier: drug/biological amount discarded/not administered to any patient – frequently asked questions. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf. Accessed December 7, 2020.
3. Centers for Medicare & Medicaid Services (CMS). 2019 Alpha-numeric HCPCS file. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2019-Alpha-Numeric-HCPCS-File.zip. Accessed September 10, 2019.
4. U.S. Food and Drug Administration (FDA). National Drug Code directory. https://www.fda.gov/drugs/informationondrugs/ucm142438.htm. Accessed September 10, 2019.
5. TRAZIMERA [package insert]. New York, NY: Pfizer Inc.; 2020.
6. American Medical Association. 2019 CPT Professional Edition. Current Procedural Terminology (CPT®) copyright 2018 by the American Medical Association. All rights reserved. Chicago, IL: AMA; 2018.
7. Centers for Medicare & Medicaid Services. Transmittal 167. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R167CP.pdf. Accessed September 10, 2019.
8. Research Data Assistance Center (ResDAC). Revenue center code. https://www.resdac.org/sites/resdac.umn.edu/files/Revenue%20Center%20Code%20Table.txt. Accessed September 10, 2019.
9. Centers for Medicare & Medicaid Services (CMS). 2020 ICD-10-CM. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM.html. Accessed September 10, 2019.

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IMPORTANT SAFETY INFORMATION

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**

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

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

Continued on the next page

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IMPORTANT SAFETY INFORMATION (Continued)

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

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

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.

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