Resource Guide

KANJINTI™ is a biosimilar to Herceptin®
backed by Amgen expertise[1]

INDICATIONS

Adjuvant Breast Cancer

KANJINTI™ 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 treatment 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 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

KANJINTI™ 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 trastuzumab product.

Metastatic Gastric Cancer

KANJINTI™ 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 trastuzumab product.

Boxed WARNINGS:

Cardiomyopathy

- **Trastuzumab products administration 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 KANJINTI™ Discontinue KANJINTI™ treatment in patients receiving adjuvant therapy and withhold KANJINTI™ in patients with metastatic disease for clinically significant decrease in left ventricular function**

Please see full indications on pages 2 and 3 and Important Safety Information, including Boxed WARNINGS, on pages 12 and 13, and click here for full Prescribing Information.

AMGEN®

KANJINTI™
(trastuzumab-anns)
For Injection 420mg/vial multiple dose

TABLE OF CONTENTS

Amgen can provide support for institutions, including education, reimbursement assistance, and to help facilitate transitioning to KANJINTI™ (trastuzumab-anns).

Boxed WARNINGS (continued)

Infusion Reactions; Pulmonary Toxicity

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

Embryo-Fetal Toxicity

- Exposure to trastuzumab 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.

Please click here for full Prescribing Information, including Boxed WARNINGS.

SUPPLY

SUPPLY[1]

KANJINTI™ in powder form is a sterile, white to pale yellow, preservative-free lyophilized powder in a vial.

Each carton of KANJINTI™ contains either:

- **150 mg single-dose vial of KANJINTI™**
  (NDC 55513-141-01)[1]
- **420 mg multi-dose* vial of KANJINTI™**
  (NDC 55513-132-01)
  *Multi-dose when reconstituted with bacteriostatic water for injection.

KANJINTI™
(trastuzumab-anns)
For Injection 420mg/vial multiple dose

RECONSTITUTION AND PREPARATION INSTRUCTIONS

RECONSTITUTION OF KANJINTI™ (TRASTUZUMAB-ANNS) VIALS[1,2]

SUPPLY AND STORAGE	
Multiple-Dose Vials*	
Reconstituted with 20 mL BWFI,† USP containing 1.1% benzyl alcohol	**Diluted in infusion bag** with 250 mL of 0.9% sodium chloride injection, USP
Refrigerate at	
2° to 8°C (36° to 46°F)	2° to 8°C (36° to 46°F)
Maximum time: **28 days**	Maximum time: **24 hours**

*Single-use vial when reconstituted with Sterile Water for Injection

†Bacteriostatic water for injection, USP, containing 0.9%-1.1% benzyl alcohol as a preservative is allowable

If you have any questions about the reconstitution and preparation of KANJINTI™, refer to the package insert or call 1-800-77-AMGEN (1-800-772-6436). For additional information and resources, please visit KANJINTI.com

Important Safety Information *(continued)*

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.**

Please see full Important Safety Information, including Boxed WARNINGS, and click here for full Prescribing Information.

RECONSTITUTION AND PREPARATION INSTRUCTIONS *(continued)*

FOR RECONSTITUTION[1]

Use appropriate aseptic technique when performing the following reconstitution steps:

Using a sterile syringe, slowly inject the (20 mL) of diluent into the vial containing the lyophilized cake of KANJINTI™. The stream of diluent should be directed into the lyophilized cake. The reconstituted vial yields a solution for multiple-dose use, containing 21 mg/mL trastuzumab-anns KANJINTI™ if BWFI was used to reconstitute.

Swirl the vial gently to aid reconstitution. **DO NOT SHAKE.**

Slight foaming of the product may be present upon reconstitution. Allow the vial to stand undisturbed for approximately 5 minutes.

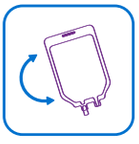
Inspect visually for particulates and discoloration prior to administration. The solution should be free of visible particulates, clear to slightly opalescent, and colorless to pale yellow.

Store KANJINTI™ reconstituted with diluent in the refrigerator at 2°C to 8°C (36°F to 46°F); discard unused KANJINTI™ after 28 days. If KANJINTI™ is reconstituted with SWFI without preservative, use immediately and discard any unused portion.

DO NOT FREEZE.

FOR DILUTION[1]

Determine the dose (mg) of KANJINTI™. Calculate the volume of the 21 mg/mL reconstituted KANJINTI™ solution needed, withdraw this amount from the vial and add it to an infusion bag containing 250 mL of 0.9% Sodium Chloride, USP. **DO NOT USE DEXTROSE (5%) SOLUTION.**



Gently invert the bag to mix the solution. The solution of KANJINTI™ for infusion, diluted in polyvinylchloride or polyethylene bags containing 0.9% Sodium Chloride Injection, USP, should be stored at 2° to 8°C (36° to 46°F) for no more than 24 hours prior to use. This storage time is additional to the time allowed for the reconstituted vials.[1]

DO NOT FREEZE.

Important Safety Information *(continued)*

- 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 left ventricular ejection fraction (LVEF)
- Discontinue KANJINTI™ treatment in patients receiving adjuvant breast cancer therapy and withhold KANJINTI™ in patients with metastatic disease for clinically significant decrease in left ventricular function

KANJINTI™
(trastuzumab-anns)
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IV INFUSION DURATION, DOSING, AND SCHEDULES

ADJUVANT TREATMENT, BREAST CANCER

WITH PACLITAXEL OR DOCETAXEL

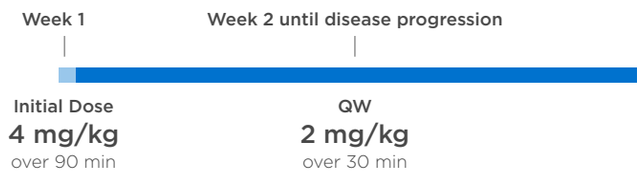
WITH DOCETAXEL AND CARBOPLATIN

AS SINGLE AGENT*

* Within 3 weeks following completion of all chemotherapy.

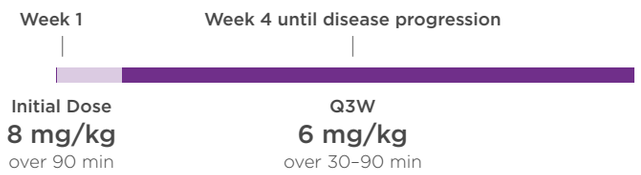
METASTATIC BREAST CANCER

AS SINGLE AGENT OR WITH PACLITAXEL



METASTATIC GASTRIC CANCER

AS SINGLE AGENT



IV = intravenous; QW = once a week; Q3W = once every 3 weeks.

Important Safety Information *(continued)*

Cardiac Monitoring

- **Evaluate cardiac function prior to and during treatment. For adjuvant breast cancer therapy, also evaluate cardiac function after completion of KANJINTI™**
- Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan

Please see full Important Safety Information, including Boxed WARNINGS, and click here for full Prescribing Information.

GENERAL CODING INFORMATION

NATIONAL DRUG CODES (NDCs)[1]

BILLING	Each single-dose carton contains one vial of KANJINTI™ (150 mg trastuzumab-anns) NDC 55513-141-01
	Each multi-dose carton contains one vial of KANJINTI™ (420 mg trastuzumab-anns) NDC 55513-132-01

BREAST CANCER

ICD-10-CM[3]	**Malignant neoplasm of the breast**	
	Female breast	**Male breast**
	C50.011 - C50.012, C50.019 C50.111 - C50.112, C50.119 C50.211 - C50.212, C50.219 C50.311 - C50.312, C50.319 C50.411 - C50.412, C50.419 C50.511 - C50.512, C50.519 C50.611 - C50.612, C50.619 C50.811 - C50.812, C50.819 C50.911 - C50.913, C50.919	C50.021 - C50.022, C50.029 C50.121 - C50.122, C50.129 C50.221 - C50.222, C50.229 C50.321 - C50.322, C50.329 C50.421 - C50.422, C50.429 C50.521 - C50.522, C50.529 C50.621 - C50.622, C50.629 C50.821 - C50.822, C50.829 C50.921 - C50.922, C50.929
HCPCS[4]	Q5117 injection, trastuzumab-anns, biosimilar, (KANJINTI™), 10 mg	
CPT[5]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

METASTATIC GASTRIC CANCER

ICD-10-CM[3]	**Malignant neoplasm of the stomach**				
	C16.0 C16.1	C16.2 C16.3	C16.4 C16.5	C16.6 C16.7	C16.8 C16.9
HCPCS[4]	Q5117 injection, trastuzumab-anns, biosimilar, (KANJINTI™), 10 mg				
CPT[5]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.				
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.				
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.				

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

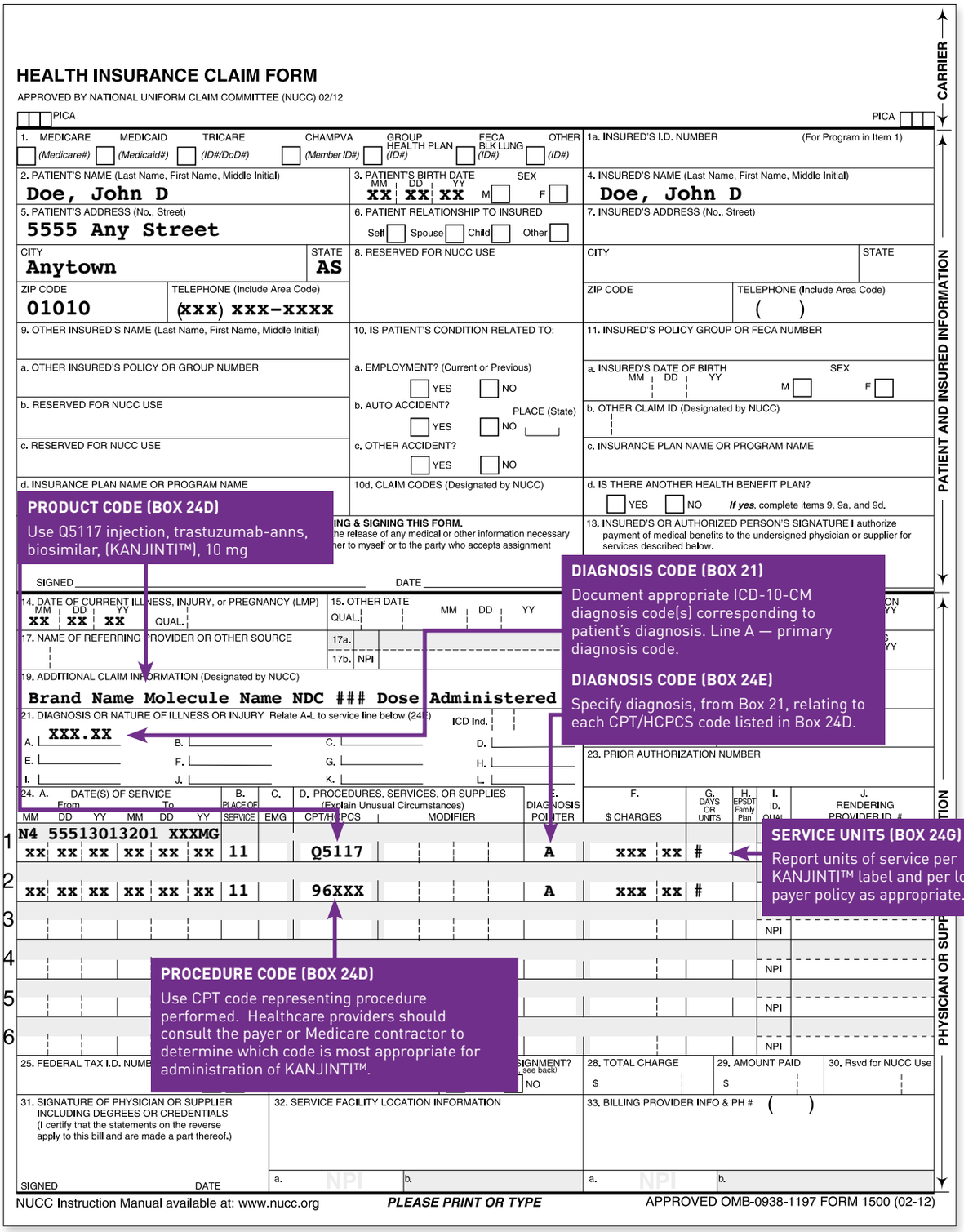
ICD = international classification of diseases; HCPCS = healthcare common procedure coding system; CPT = current procedural terminology.

Important Safety Information *(continued)*

- Monitor frequently for decreased left ventricular function during and after KANJINTI™ treatment
- Monitor more frequently if KANJINTI™ is withheld for significant left ventricular cardiac dysfunction

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



PRODUCT CODE (BOX 24D)

Use Q5117 injection, trastuzumab-anns, biosimilar, (KANJINTI™), 10 mg

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

Report units of service per KANJINTI™ label and per local payer policy as appropriate.

PROCEDURE CODE (BOX 24D)

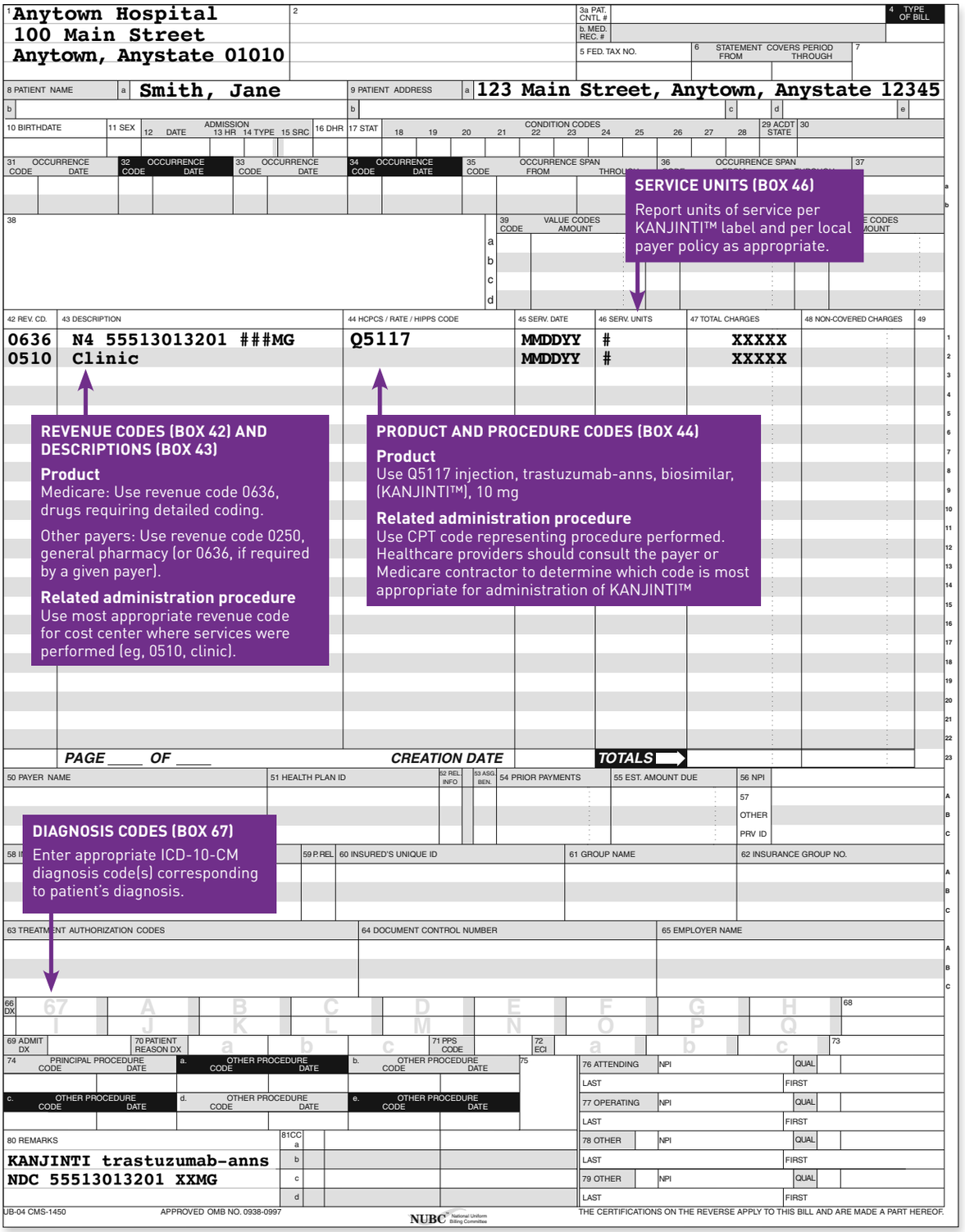
Use CPT code representing procedure performed. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of KANJINTI™.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

HOSPITAL CODING FORM

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



SERVICE UNITS (BOX 46)

Report units of service per KANJINTI™ label and per local payer policy as appropriate.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)

Product

Medicare: Use revenue code 0636, drugs requiring detailed coding.

Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).

Related administration procedure

Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)

Product

Use Q5117 injection, trastuzumab-anns, biosimilar, (KANJINTI™), 10 mg

Related administration procedure

Use CPT code representing procedure performed. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of KANJINTI™

DIAGNOSIS CODES (BOX 67)

Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.

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KANJINTI™ (trastuzumab-anns) For Injection 420mg/vial multiple dose

KANJINTI™ (TRASTUZUMAB-ANNS) PRODUCT FACT SHEET

See full Indications, Boxed WARNINGS, and additional Important Safety Information on following pages.

PRODUCT INFORMATION

NDC	Description	Quantity
NDC 55513-141-01	150 mg single-dose vial of KANJINTI™	One per carton
NDC 55513-132-01	420 mg multi-dose vial of KANJINTI™	One per carton

STORAGE AND HANDLING REQUIREMENTS

KANJINTI™ vials must be stored in the refrigerator at 2° to 8°C (36° to 46°F) until time of reconstitution.
DO NOT FREEZE.

SHIPPING CONTAINER INFORMATION

KANJINTI™ should be unpacked and refrigerated.

KANJINTI™ should not be stored in the shipping container.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

PRODUCT CODE

Q5117 injection, trastuzumab-anns, biosimilar, (KANJINTI™), 10 mg

SUPPLIED AND MARKETED BY

Amgen USA Inc.

amgen.com

KANJINTI.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Amgen Assist®: 1-888-4ASSIST (1-888-427-7478) or www.AmgenAssistOnline.com

Please see full Important Safety Information, including Boxed WARNINGS, and click here for full Prescribing Information.

SUPPORT PROGRAMS

AMGEN ASSIST 360™

Support, Simplified

See How We Can Help Your Patients

Offering the tools, information, and support for Amgen products that make a difference for you and your patients

AMGEN REIMBURSEMENT SPECIALISTS

Connect with an Amgen Reimbursement Counselor or schedule a visit with a Field Reimbursement Specialist

PATIENT RESOURCE GUIDE

Find co-pay and reimbursement resources* for patients with different kinds of insurance, or no insurance at all

BENEFIT VERIFICATION

Submit, store, and retrieve benefit verifications for all your patients currently on an Amgen product

*Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

CALL 1-888-4ASSIST (888-427-7478)
Monday to Friday, 9:00 AM to 8:00 PM ET,
OR VISIT AMGENASSIST360.COM

KANJINTI™
(trastuzumab-anns)
For Injection 420mg/vial multiple dose

IMPORTANT SAFETY INFORMATION

Boxed WARNINGS and Additional Important Safety Information

Cardiomyopathy

- **Trastuzumab products administration 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 KANJINTI™. Discontinue KANJINTI™ treatment in patients receiving adjuvant therapy and withhold KANJINTI™ in patients with metastatic disease for clinically significant decrease in left ventricular function**

Infusion Reactions; Pulmonary Toxicity

- **Trastuzumab products administration can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt KANJINTI™ infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue KANJINTI™ 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 ventricular ejection fraction (LVEF)
- Discontinue KANJINTI™ treatment in patients receiving adjuvant breast cancer therapy and withhold KANJINTI™ 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 KANJINTI™**
- 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 KANJINTI™ treatment
- Monitor more frequently if KANJINTI™ is withheld for significant left ventricular cardiac dysfunction

Infusion Reactions

- **KANJINTI™ administration can result in serious and fatal infusion reactions**
- **Symptoms usually occur during or within 24 hours of KANJINTI™ administration**
- **Interrupt KANJINTI™ infusion for dyspnea or clinically significant hypotension**
- **Monitor patients until symptoms completely resolve**
- **Discontinue KANJINTI™ for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.**

Please click here for full Prescribing Information, including Boxed WARNINGS.

KANJINTI™
(trastuzumab-anns)
For Injection 420mg/vial multiple dose

IMPORTANT SAFETY INFORMATION *(continued)*

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 KANJINTI™
- Advise pregnant women and females of reproductive potential that exposure to KANJINTI™ 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 KANJINTI™. Advise female patients to contact their healthcare provider with a known or suspected pregnancy
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for KANJINTI™ treatment and any potential adverse effects on the breastfed child from KANJINTI™ or from the underlying maternal condition

Pulmonary Toxicity

- **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 KANJINTI™ in patients experiencing pulmonary toxicity

Exacerbation of Chemotherapy-Induced Neutropenia

- In randomized, controlled clinical trials, the 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.

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Amgen at 1-800-772-6436.

Please click here for full Prescribing Information, including Boxed WARNINGS.

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Please see full Important Safety Information, including Boxed WARNINGS, and click here for full Prescribing Information.

Please visit **KANJINTI.com** for additional information and resources.

Call **1-800-77-AMGEN (1-800-772-6436)** if you have questions about ordering and accessing KANJINTI™.

Reimbursement Disclaimer

This resource is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

References: 1. KANJINTI™ (trastuzumab-anns) Prescribing Information, Amgen. https://www.pi.amgen.com/united_states/kanjinti/kanjinti_pi.pdf. **2.** Herceptin® (trastuzumab) Prescribing Information [revised 2017], Genentech. **3.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/icd10cm_index_2019.pdf. Accessed April 2, 2019. **4.** Healthcare Common Procedure Coding System (HCPCS). HCPCS Code J3590. https://hcpcs.codes/j-codes/J3590/. Accessed April 2, 2019. **5.** American Medical Association. 2018 Professional Edition, Current Procedural Terminology (CPT) copyright 2016 American Medical Association. All rights reserved.

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