CODING AND BILLING GUIDE FOR *ONTRUZANT*® (trastuzumab-dttb)

Programmed with links to help you find the information you need faster

Before prescribing ONTRUZANT, please read the Selected Safety Information on pages 3–6 and the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.

ORGANON

Ontruzant®
trastuzumab-dttb
for injection, for intravenous use 21 mg/mL

Included are lists of codes that may be relevant for ONTRUZANT and its administration. This information is current as of August 2023. The information provided here is compiled from sources believed to be accurate, but Organon makes no representation that it is accurate. Information about Healthcare Common Procedure Coding System (HCPCS) codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS) applicable to Medicare Part B and may not apply to other public or private payers. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes. This information is subject to change. Organon cautions that payer coding requirements vary and can frequently change, so it is important to regularly check with each payer or, where applicable, the Medicare Administrative Contractor, as to payer-specific requirements.

You are solely responsible for determining the appropriate codes and for any action you take in billing. The information provided here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. Organon and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs.

Diagnosis codes should be selected only by a health care professional. Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payers' guidelines. Although CMS has said that an unspecified code may be appropriate in some cases, CMS has advised that you should always code with as much specificity as possible, consistent with the clinical documentation.

INDICATIONS AND SELECTED SAFETY INFORMATION

INDICATIONS AND USAGE

Adjuvant Breast Cancer

ONTRUZANT 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 consisting of 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.

Metastatic Breast Cancer

ONTRUZANT 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

ONTRUZANT 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.

SELECTED SAFETY INFORMATION

CARDIOMYOPATHY

- **Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving a trastuzumab product with anthracycline-containing chemotherapy regimens.**
- **Evaluate left ventricular function in all patients prior to and during treatment with ONTRUZANT. Discontinue ONTRUZANT treatment in patients receiving adjuvant therapy and withhold ONTRUZANT 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 ONTRUZANT infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue ONTRUZANT for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.**

ER/PR, estrogen receptor/progesterone receptor; FDA, US Food and Drug Administration; HER2, human epidermal growth factor receptor 2.

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SELECTED 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.**

WARNINGS AND PRECAUTIONS

CARDIOMYOPATHY

- **Administration of trastuzumab products can result in subclinical 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 congestive heart failure (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 left ventricular ejection fraction (LVEF).
- **Discontinue ONTRUZANT treatment in patients receiving adjuvant breast cancer therapy and withhold ONTRUZANT 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 ONTRUZANT.**
- Conduct a 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 ONTRUZANT treatment.
- Monitor more frequently if ONTRUZANT 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 ONTRUZANT administration.**
- **Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension.**
- **Monitor patients until symptoms completely resolve.**
- **Discontinue ONTRUZANT 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.

MUGA, multigated acquisition.

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SELECTED 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 ONTRUZANT.
- Advise pregnant women and females of reproductive potential that exposure to ONTRUZANT 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 ONTRUZANT.
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for ONTRUZANT treatment and any potential adverse effects on the breastfed child from ONTRUZANT 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 ONTRUZANT 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.

DRUG INTERACTIONS

- Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period based on population PK analysis. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully.

NCI-CTC, National Cancer Institute - Common Terminology Criteria; PK, pharmacokinetics.

SELECTED SAFETY INFORMATION (*continued*)

ADVERSE REACTIONS

- The most common adverse reactions associated with trastuzumab products in the adjuvant and metastatic breast cancer setting are 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 the gastric cancer setting were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

CONTENTS

Click the arrows to be taken to specific billing, coding, and product information.

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NDCs AND BILLING CODES FOR *ONTRUZANT*® (trastuzumab-dttb)

Click the Home button to return to the Contents page

NDCs and Packaging Information

The NDC is typically required when submitting a medical drug claim with a miscellaneous HCPCS code. Please consult with the payer to understand specific billing requirements.

PRODUCT	PACKAGE	NDC EFFECTIVE UPON PRODUCT AVAILABILITY
ONTRUZANT® (trastuzumab-dttb) for injection 150 mg	Carton with one 150-mg vial, single-dose	78206-0147-01
ONTRUZANT® (trastuzumab-dttb) for injection 420 mg	Carton with one 420-mg vial, multi-dose	78206-0148-01

Please note: The NDCs above are the billable NDCs that appear on the cartons. The NDCs on the vial should not be used for billing purposes.

NDC, National Drug Code.

NDCs AND BILLING CODES FOR *ONTRUZANT®* (trastuzumab-dttb) (*continued*)

Billing Codes

Below is a list of possible codes that could be relevant for ONTRUZANT and its administration. Please consult with the applicable payer to understand the payer's specific billing requirements.

HCPCS Code for ONTRUZANT

HCPCS CODE	DESCRIPTOR
Q5112[1]	Injection, trastuzumab-dttb, biosimilar (ONTRUZANT), 10 mg[1]

For questions on billing if a portion of a single-use package is wasted, consult the applicable payer's policy regarding wastage. Record the amount of drug administered and the amount wasted in the patient's medical record. Medicare requires the use of the JW modifier on all claims that include wasted product. Effective July 1, 2023, Medicare requires the use of the JZ modifier on all claims for single-use packages when there are no discarded amounts.[2]

Revenue Code–For Use in the Hospital Setting

REVENUE CODE	DESCRIPTOR
0636	Drugs requiring detailed coding[3]

CPT® Codes for Administration

CPT CODE	DESCRIPTOR
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug[4]
96415	Chemotherapy administration, intravenous infusion technique; each additional hour[5]
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour[6]

JW modifier, Drug Amount Discarded/Not Administered to Any Patient; JZ modifier, Zero Drug Amount Discarded/Not Administered to Any Patient; CPT, Current Procedural Terminology.

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POSSIBLE RELEVANT DIAGNOSIS CODES FOR BREAST CANCER AND GASTRIC CANCER[7]

The following codes are provided as a reference and may be relevant when billing for ONTRUZANT and its administration. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of its use and for information on additional codes. Diagnosis codes should be selected only by a health care professional. You are solely responsible for determining the appropriate codes and for any action you take in billing. When submitting a claim for ONTRUZANT, always verify coding requirements with the relevant payer. Coding requirements may vary by insurer or plan; please refer to the payer-specific policies to understand what may be covered.

Check with the relevant payer regarding guidance on which diagnoses they will recognize and the applicability of secondary codes. Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payers' guidelines. Providers should document the diagnosis with a sufficiently high degree of specificity based on the information available to enable the identification of the most appropriate code. Although CMS has said that an unspecified code may be appropriate in some cases, CMS has advised that you should always code with as much specificity as possible consistent with the clinical documentation.

Possible Relevant ICD-10-CM Diagnosis Codes for Breast Cancer

Below is a list of possible codes that could be relevant when billing for ONTRUZANT and its administration. Please consult with the applicable payer to understand the payer's specific billing requirements.

Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payer's guidelines.

TYPE	CODE	DESCRIPTION
Diagnosis: ICD-10-CM	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 the female breast
	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 the male breast

Possible Relevant ICD-10-CM Diagnosis Codes for Gastric Cancer

TYPE	CODE	DESCRIPTION
Diagnosis: ICD-10-CM	C16.0—C16.9	Malignant neoplasm of the stomach

Please see the Indications on page 3.

CMS, Centers for Medicare & Medicaid Services; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

COVERAGE AND REIMBURSEMENT INFORMATION

Commercial and Private Payer Coverage

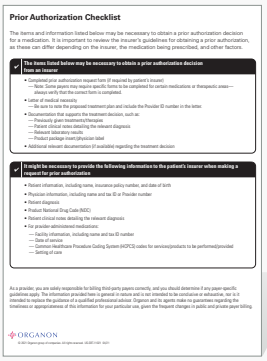
Each patient may have a unique billing situation for coverage, coding, and reimbursement that is dependent on the patient's health plan and associated benefits. Insurers may require a prior authorization, including submission of a medical necessity letter. It is important to review the insurer's guidelines for obtaining a prior authorization, as these can differ depending on the insurer, the medication being prescribed, and other factors. Please ensure the accurate completion of reimbursement- or coverage-related documentation for therapies according to the specific requirements of the patient's plan.

The Prior Authorization Checklist and Sample Prior Authorization Letter can help you to understand the documents and information that may be helpful when seeking a prior authorization. As always, you should check for payer-specific requirements.

Prior Authorization Checklist

The items listed below may be necessary to obtain a prior authorization decision from an insurer:

- Completed prior authorization request form (if required by patient's insurer)
  - Note: Some payers may require specific forms to be completed for certain medications or therapeutic areas–always verify that the correct form is completed
- Letter of medical necessity
  - Be sure to note the proposed treatment plan and include the Provider ID number in the letter
- Documentation that supports the treatment decision, such as:
  - Previously given treatments/therapies
  - Patient clinical notes detailing the relevant diagnosis
  - Relevant laboratory results
  - Product package insert/physician label
- Additional relevant documentation (if available) regarding the treatment decision


Prior Authorization Checklist

The items and information listed below may be necessary to obtain a prior authorization decision for a medication. It is important to review the insurer's guidelines for obtaining a prior authorization, as these can differ depending on the insurer, the medication being prescribed, and other factors.

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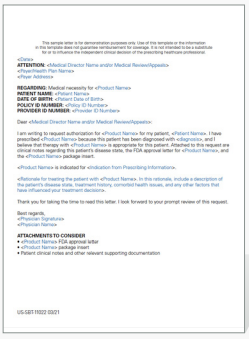
It might be necessary to provide the following information to the patient's insurer when making a request for prior authorization:

- Patient information, including name, insurance policy number, and date of birth
- Physician information, including name and tax ID or Provider number
- Patient diagnosis
- Product National Drug Code (NDC)
- Patient clinical notes detailing the relevant diagnosis
- For provider-administered medications:
  - Facility information, including name and tax ID number
  - Date of service
  - Common Healthcare Procedure Coding System (HCPCS) codes for services/products to be performed/provided
  - Setting of care

Sample Prior Authorization Letter

Insurers may require a medical necessity letter as part of the prior authorization process (see sample letter).


This sample letter is for demonstration purposes only. Use of this template or the information in this template does not guarantee reimbursement for coverage. It is not intended to be a substitute for or to influence the independent clinical decision of the prescribing healthcare professional.

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COVERAGE AND REIMBURSEMENT INFORMATION
(continued)

The Appeal Checklist and Sample Appeal Letter can help you to understand the documents and information that may be helpful when filing an appeal. As always, you should check for payer-specific requirements.

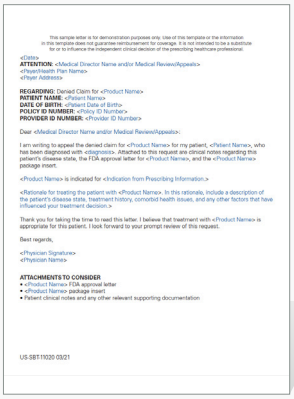
Appeal Checklist/Sample Appeal Letter

If a claim for a medication is denied, the items listed below may be helpful in the appeals process. It is important to review the denial and the insurer's guidelines, as the required documentation and process for making an appeal will be different depending on the insurer and the patient.

As a first step, ensure that the claim was completed and submitted correctly.

Always verify that:

- The product is covered by the patient's insurer for the patient's diagnosis
- A prior authorization or precertification was obtained, if required by the patient's insurer
- Patient information was recorded correctly (eg, name, date of birth, insurance policy number)
- The product was coded correctly (eg, that the correct code was used to describe the product, that the correct number of units was recorded on the claim, etc.)



This sample letter is for demonstration purposes only. Use of this template or the information in this template does not guarantee reimbursement for coverage. It is not intended to be a substitute for or to influence the independent clinical decision of the prescribing healthcare professional.

<Date>
ATTENTION: <Medical Director Name and/or Medical Review/Appeals>
<Payer/Health Plan Name>
<Payer Address>

REGARDING: Denied Claim for <Product Name>
PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY ID NUMBER: <Policy ID Number>
PROVIDER ID NUMBER: <Provider ID Number>

Dear <Medical Director Name and/or Medical Review/Appeals>:

I am writing to appeal the denied claim for <Product Name> for my patient, <Patient Name>, who has been diagnosed with <diagnosis>. Attached to this request are clinical notes regarding this patient's disease state, the FDA-approved letter for <Product Name>, and the <Product Name> package insert.

<Product Name> is indicated for <Indication from Prescribing Information.>

<Rationale for treating the patient with <Product Name>. In this rationale, include a description of the patient's disease state, treatment history, comorbid health issues, and any other factors that have influenced your treatment decision.>

Thank you for taking the time to read this letter. I believe that treatment with <Product Name> is appropriate for this patient. I look forward to your prompt review of this request.

Best regards,

<Physician Signature>
<Physician Name>

ATTACHMENTS TO CONSIDER
- <Product Name> FDA approval letter
- <Product Name> package insert
- Patient clinical notes and any other relevant supporting documentation

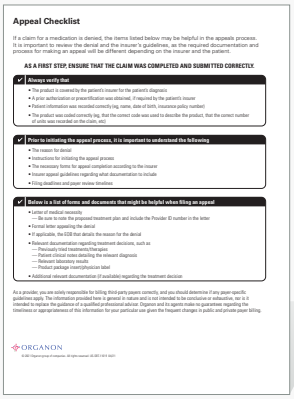
US-SBT-11020 03/21

Prior to initiating the appeal process, it is important to understand the following:

- The reason for denial
- Instructions for initiating the appeal process
- The necessary forms for appeal completion according to the insurer
- Insurer appeal guidelines regarding what documentation to include
- Filing deadlines and payer review timelines

Below is a list of forms and documents that might be helpful when filing an appeal:

- Letter of medical necessity
  - – Be sure to note the proposed treatment plan and include the Provider ID number in the letter
- Formal letter appealing the denial
- If applicable, the EOB that details the reason for the denial
- Relevant documentation regarding treatment decisions, such as:
  - – Previously tried treatments/therapies
  - – Patient clinical notes detailing the relevant diagnosis
  - – Relevant laboratory results
  - – Product package insert/physician label
- Additional relevant documentation (if available) regarding the treatment decision



Appeal Checklist

If a claim for a medication is denied, the items listed below may be helpful in the appeals process. It is important to review the denial and the insurer's guidelines, as the required documentation and process for making an appeal will be different depending on the insurer and the patient.

AS A FIRST STEP, ENSURE THAT THE CLAIM WAS COMPLETED AND SUBMITTED CORRECTLY.

✔ Always verify that
- The product is covered by the patient's insurer for the patient's diagnosis
- A prior authorization or precertification was obtained, if required by the patient's insurer
- Patient information was recorded correctly (eg, name, date of birth, insurance policy number)
- The product was coded correctly (eg, that the correct code was used to describe the product, that the correct number of units was recorded on the claim, etc)

✔ Prior to initiating the appeal process, it is important to understand the following
- The reason for denial
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  - — Relevant laboratory results
  - — Product package insert/physician label
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As a provider, you are solely responsible for billing third-party payers correctly, and you should determine if any payer-specific guidelines apply. The information provided here is general in nature and is not intended to be conclusive or exhaustive, nor is it intended to replace the guidance of a qualified professional advisor. Organon and its agents make no guarantees regarding the timelines or appropriateness of this information for your particular use given the frequent changes in public and private payer billing.

EOB, Explanation of Benefits.

COVERAGE AND REIMBURSEMENT INFORMATION
(continued)

The Organon Access Program for ONTRUZANT

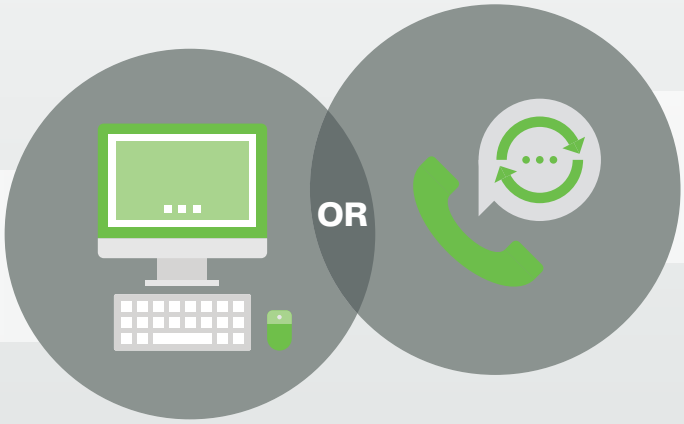
CAN HELP ANSWER QUESTIONS ABOUT

- Benefit investigations
- Billing and coding
- Co-pay assistance for eligible patients
- Prior authorizations and appeals
- Referral to the Organon Patient Assistance Program for eligibility determination (provided through the Organon Patient Assistance Program Inc.)
- Product distribution

You can also request to be contacted by a Field Reimbursement Manager.

The Organon Access Program is available online and via a toll-free telephone number

For more information, visit organonaccessprogram-ontruzant.com



Call 844-326-2986,
Monday through Friday, 8 AM to 8 PM ET

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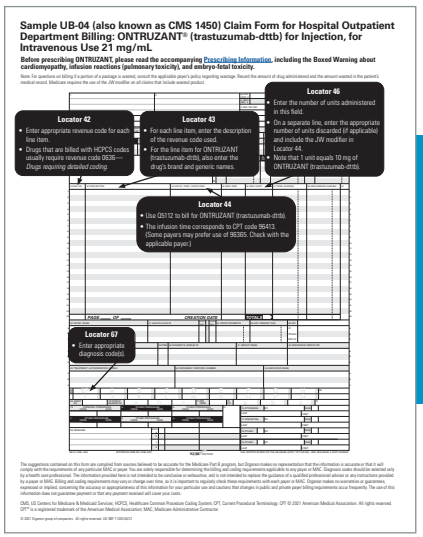
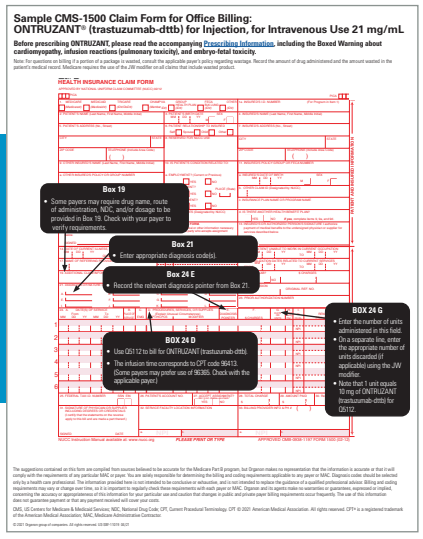
SAMPLE CLAIM FORMS

Click images to download Sample Claim Forms.



This is a sample UB-04 (CMS-1450) paper claim for hospital outpatient billing. Sample forms can be found at organonaccessprogram-ontruzant.com.



This is a sample CMS-1500 paper claim for office billing. Sample forms can be found at organonaccessprogram-ontruzant.com.

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INFUSION REACTIONS; PULMONARY TOXICITY

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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.**

Before prescribing ONTRUZANT, please read the Selected Safety Information on pages 3–6 and the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.

REFERENCES

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Ontruzant®
trastuzumab-dttb
for injection, for intravenous use 21 mg/mL