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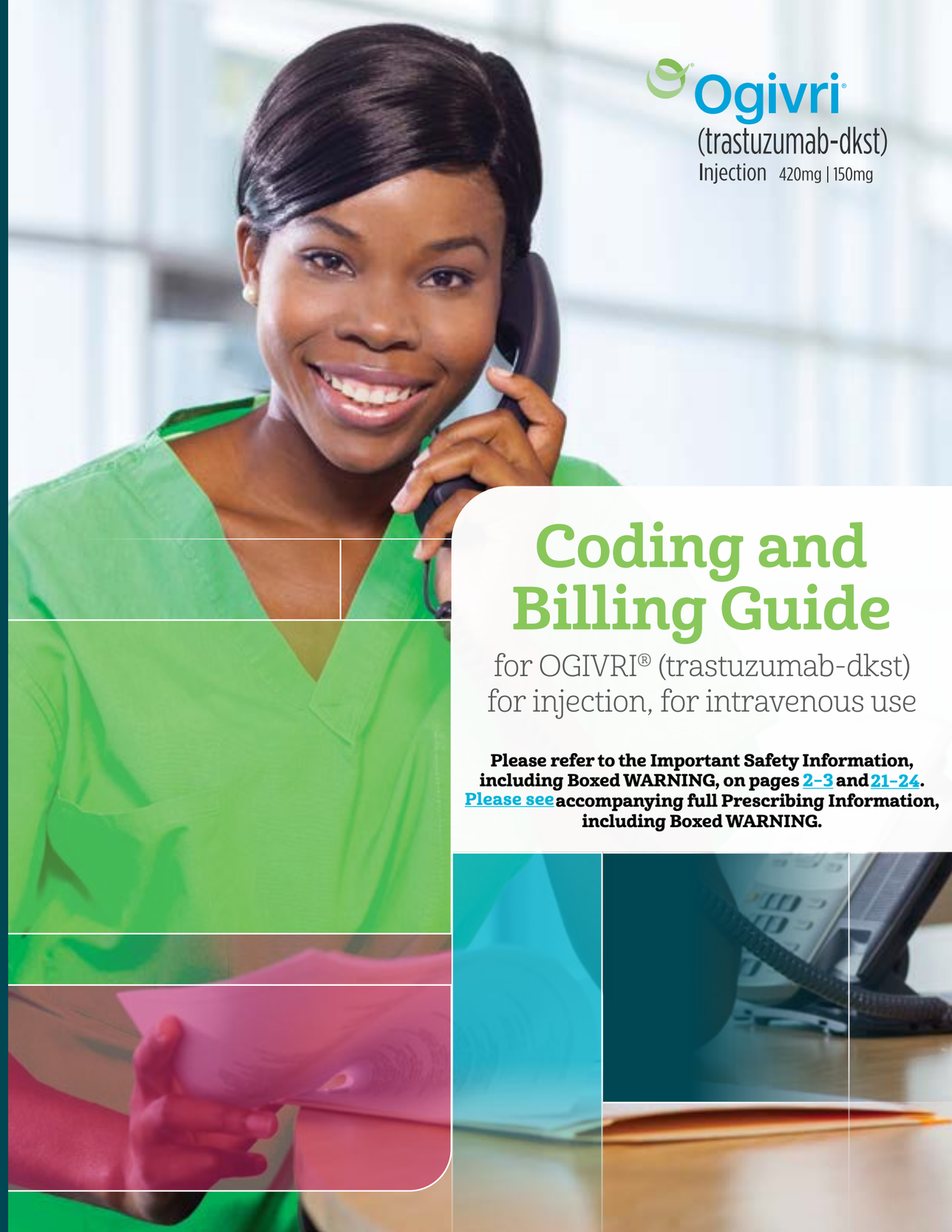
TRA-2023-00115-US

Biocon Biologics™



Ogivri®
(trastuzumab-dkst)
Injection 420mg | 150mg

Coding and Billing Guide

for OGIVRI® (trastuzumab-dkst) for injection, for intravenous use

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Ogivri®
(trastuzumab-dkst)
Injection 420mg | 150mg

Table of Contents

Purpose of Guide and Disclaimer 1

Indications 2

Coding 4

Reporting Use of OGIVRI (trastuzumab-dkst) 4

Healthcare Common Procedure Coding System (HCPCS) Level II Codes 4

Modifiers for Products Acquired via 340B Drug Discount Program 4

National Drug Codes (NDCs) 5

Reporting Administration of OGIVRI 5

Diagnosis Coding 6

Reporting Revenue Codes 8

Coverage 9

Reimbursement 10

Medicare 10

Physician Office 10

Hospital Outpatient Departments 10

Commercial Payers, Medicare Advantage, and Medicaid Plans 12

Sequestration 12

Claims 13

Sample CMS-1500 Claim Form 14

Sample CMS-1450 (UB-04) Claim Form 16

Sample Letters 17

Sample Letter of Medical Necessity 18

Sample Appeal Letter 20

Important Safety Information 21

References 25

Purpose of Guide and Disclaimer

This Coding and Billing Guide for OGIVRI (trastuzumab-dkst) for injection, for intravenous use, is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare professionals and their staff who prescribe and administer OGIVRI at physician office and hospital outpatient sites of care. OGIVRI is a biosimilar to HERCEPTIN® (trastuzumab) for the indications listed on page 2.

The content provided in this guide is for informational purposes and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure that OGIVRI claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios and Biocon Biologics does not guarantee OGIVRI coverage or reimbursement.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of February 2023.

My Biocon Biologics™

MY BIOCON BIOLOGICS® provides patient access support services and can assist with patient-specific verification of benefits for OGIVRI and its associated services, such as infusion administration. For assistance:

Call
1 (833) 695-2623

Log on to
www.mybioconbiologicsportal.com

Indications[1]

Adjuvant Breast Cancer:

OGIVRI 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
- 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 OGIVRI.

* 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:

OGIVRI 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 OGIVRI.

Metastatic Gastric Cancer:

OGIVRI 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 OGIVRI.

How Supplied:

OGIVRI is supplied as 150 mg lyophilized powder in a single-use vial for reconstitution and in a 420 mg lyophilized powder in a multiple-dose vial for reconstitution.

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOMYOPATHY, INFUSION REACTIONS, EMBRYO-FETAL TOXICITY, and PULMONARY TOXICITY

Cardiomyopathy

Administration of OGIVRI can result in sub-clinical and clinical cardiac failure. The incidence and severity are highest in patients receiving OGIVRI with anthracycline-containing chemotherapy regimens.

Evaluate left ventricular function in all patients prior to and during treatment with OGIVRI. Discontinue OGIVRI treatment in patients receiving adjuvant therapy and withhold OGIVRI in patients with metastatic disease for clinically significant decrease in left ventricular function.

Infusion Reactions; Pulmonary Toxicity

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

Embryo-Fetal Toxicity

Exposure to OGIVRI 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 refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Coding

It is critical to report medical codes that accurately reflect a patient's condition, treatment, and services rendered when submitting a claim form to a payer. The codes in this section may be appropriate to report use of OGIVRI and its administration.

Reporting Use of OGIVRI

Healthcare Common Procedure Coding System (HCPCS) Level II Codes[2]

OGIVRI has been assigned a unique HCPCS code, **Q5114 Injection, trastuzumab-dkst, biosimilar (OGIVRI), 10 mg**.

Table 1. HCPCS Code Appropriate for OGIVRI

Code	Description	Sites of Service	Payers
Q5114	Injection, trastuzumab-dkst, biosimilar (OGIVRI), 10 mg	Physician office and hospital outpatient department	Most payers

Modifiers for Products Acquired via 340B Drug Discount Program

The Centers for Medicare & Medicaid Services (CMS) has established modifiers that must be reported on claims that meet the following criteria:

The drugs were furnished to a patient enrolled in fee-for-service (FFS) Medicare Part B

The drugs were administered in the hospital outpatient setting

The drugs were acquired via the 340B Drug Discount Program

The following modifiers may be appropriate to bill along with the HCPCS code for OGIVRI:

Table 2. Medicare Modifiers for 340B Drugs in the Hospital Outpatient Setting[3]

Modifier	Description
-JG	Drug or biological acquired with 340B drug pricing program discount
-TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

National Drug Codes (NDCs)

For approved medications, the FDA assigns a 3-segment number known as the NDC that is specific to the labeler (manufacturer), product (identifies a specific drug, strength, and dosage formulation), and package size. OGIVRI (trastuzumab-dkst) has been assigned 10-digit NDCs as listed in the package insert. The 11-digit format is required by the Health Insurance Portability and Accountability Act for claims submission and is typically reported on claims without hyphens or other punctuation marks.

Table 3. NDCs for OGIVRI[1]

Product	NDC (10-Digit Format)	NDC (11-Digit Format)
OGIVRI (trastuzumab-dkst) for injection 150 mg/vial supplied in a single-use vial	83257-001-11	83257-**0**001-11
OGIVRI (trastuzumab-dkst) for injection 420 mg/vial supplied in a multiple-dose vial	83257-004-12	83257-**0**004-12

Report the NDC as required by payers and/or your billing systems. For example, state Medicaid agencies usually require 11-digit NDCs on claims, even after a unique HCPCS code has been assigned. Some state Medicaid agencies require healthcare providers to bill the NDC and other information (e.g., an NDC qualifier, a unit of measure, and a unit of measure qualifier, in addition to the HCPCS code). Furthermore, the NDC location on the claim form may vary by payer. **Please contact payers directly to verify requirements or call My Biocon Biologics at 1 (833) 695-2623 for assistance.**

Reporting Administration of OGIVRI

If a treating healthcare professional decides to administer OGIVRI in either the physician office or hospital outpatient sites of care, drug administration services are reported to most payers with Current Procedural Terminology (CPT®)[4] codes. The following CPT codes may be used to report the infusion service.

Table 4. CPT Codes for OGIVRI Infusion Procedure

Code	Description	Site(s) of Service
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Physician office and hospital outpatient
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	

Diagnosis Coding

The diagnosis related to the patient's treatment with OGIVRI is reported on physician and hospital claims with International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes.[5]

Some payers require more than one ICD-10-CM code and may require one to be selected as the primary diagnosis code. **Please call My Biocon Biologics at 1 (833) 695-2623 for assistance or contact payers directly to verify payer-specific requirements.**

Table 5. ICD-10-CM Codes for OGIVRI

Code	Description
Breast Cancer	
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Table 5. ICD-10-CM Codes for OGIVRI (cont.)

Code	Description
Breast Cancer (cont.)	
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Additional code to identify estrogen receptor status	
Z17.0	Estrogen receptor positive status [ER+]
Z17.1	Estrogen receptor negative status [ER-]

Table 5. ICD-10-CM Codes for OGIVRI (cont.)

Code	Description
Additional code to identify hormone sensitivity malignancy status	
Z19.1	Hormone sensitive malignancy status
Z19.2	Hormone resistant malignancy status
Gastric/Gastroesphageal adenocarcinoma	
C15.5	Malignant neoplasm of lower third of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified

Reporting Revenue Codes

Revenue codes categorize hospital services by revenue center to capture cost data. For many payers, claims must include a revenue code for each service provided in the hospital. Below are sample revenue codes that may be relevant for OGIVRI and its administration in the hospital outpatient site of care.

Table 6. Sample Revenue Codes

Code[6]	Description	Appropriate Use
0636	Drugs requiring detailed coding	Used in combination with HCPCS code
0510	Clinic visit	Used in combination with CPT injection code

Key: CPT - Current Procedural Terminology; HCPCS - Healthcare Common Procedure Coding System.

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Coverage

Importance of Benefit Verifications

It is important to complete a thorough investigation of insurance benefits to determine coverage every time a patient presents for treatment with OGIVRI (trastuzumab-dkst). A benefit verification will establish whether the patient's coverage is effective at the time of service, help determine plan coverage of the drug, and report any applicable utilization management or acquisition requirements.

OGIVRI is covered by most major payers, including Medicare, Medicaid, and private commercial plans. Please consult your local Medicare Administrative Contractor (MAC) or other plan administrator for coverage guidance.

My Biocon Biologics™

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Reimbursement

Medicare

Medicare provides separate payment for certain Part B-covered drugs in outpatient sites of service. The following section provides general reimbursement information; please consult with your MAC for more information on Medicare policies that may affect reimbursement of OGIVRI.

Physician Office

Medicare reimburses for Part B-covered drugs administered in the physician office setting based on average sales price (ASP), which is reported quarterly by manufacturers and updated by CMS.

For new-to-market drugs, it normally takes about 2 quarters, or around 6 months, for ASP to be established. Until ASP is established, payment is based on wholesale acquisition cost (WAC).

Table 7. Medicare Reimbursement Methodology for Part B-Covered Biosimilars in the Physician Office Setting

Medicare Physician Office Payment Methodology[7]	When This Applies
103% of WAC of biosimilar	If a drug does not yet have an established ASP
ASP of biosimilar + 6% of reference product's ASP	For drugs with an established ASP

Key: ASP - average sales price; WAC - wholesale acquisition cost.

Hospital Outpatient Departments

Medicare payment for Part B-covered biosimilar drugs administered in hospital outpatient clinics varies based on multiple factors, including[8]:

Whether the biosimilar has an established ASP

- It can take 6 months or more for ASP to be established for a new product

Whether the biosimilar has temporary pass-through status

- Pass-through status may be awarded to biosimilars and typically lasts between 2 and 3 years

Whether the drug is administered in a facility that participates in the federal 340B drug discount program

- The 340B program offers deeply discounted prices to qualifying facilities that meet special criteria

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

The following table provides an overview of Medicare reimbursement methodology for biosimilars under the Outpatient Prospective Payment System (OPPS):

Table 8. Payment Methodology for Biosimilars Administered Under OPPS[8]

Biosimilar has a WAC as published in pricing compendia?	Biosimilar has an established ASP?	Biosimilar has pass-through status?	Biosimilar was acquired by the facility through the 340B drug discount program?	2021 Medicare OPPS Reimbursement Methodology*
✗	✗	✗	✗	95% of AWP
✗	✗	✗	✓	AWP – 69.46%
✓	✗	✗	✗	WAC + 3%
✓	✗	✗	✓	WAC – 22.5%
✓	✓	✗	✗	ASP + 6% of reference product's ASP
✓	✓	✗	✓	ASP – 22.5%
✓	✓	✓	✗	ASP + 6% of reference product's ASP
✓	✓	✓	✓	ASP + 6% of reference product's ASP

*Last policy update: April 2, 2018.

ASP – average sales price; AWP – average wholesale price; WAC –wholesale acquisition cost.

✓ Yes ✗ No

Commercial Payers, Medicare Advantage, and Medicaid Plans

Many payers, including commercial insurance providers, Medicare Advantage, and managed Medicaid plans, reimburse physicians and hospitals based on individual contracts that are negotiated between the healthcare provider and the payer. It is particularly important for physician practices and hospital outpatient facilities to review their contracts for language that specifies how the payer will calculate reimbursement for new drugs. FFS Medicaid plans, like FFS Medicare, typically publicize their payment rates via a fee schedule.

Payers may reimburse physician-administered drugs and associated services in a variety of ways, including:

- Fee schedule
- Invoice
- AWP minus a percentage
- Percentage of billed charges
- ASP plus a percentage
- Usual, customary, and reasonable rates
- WAC plus a percentage
- Bundled payment rate
- Other or hybrid methodology

Sequestration

Please note that due to across-the-board cuts in federal spending known as sequestration, Medicare covers 80% of the payment to providers, which is reduced by 2%. This affects payment for Part B-covered drugs along with payment for professional services, such as the OGIVRI (trastuzumab-dkst) injection administration service. Sequestration does not affect the patient's share of cost, which, under FFS Medicare Part B, is a 20% coinsurance after the annual deductible.[9]

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Claims

Sample CMS-1500 Claim Form

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or the electronic claim file (837P). Required information includes patient demographic and insurance information, insurance policy number, codes to indicate the services and products provided to the patient, and the provider's National Provider Identifier (NPI). Reported codes (e.g., ICD-10-CM, CPT, and HCPCS codes) must be supported by the information in the patient's medical record. Filling out an accurate and complete claim form is critical for timely processing and reimbursement of your claim. A sample CMS-1500 claim form for billing OGIVRI (trastuzumab-dkst) is provided.

Please note that information specific to coding and payment is subject to change and should be verified for each patient prior to treatment. Information presented here is current as of February 2023.

The content provided on this sample claim form is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure OGIVRI claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios and Biocon Biologics does not guarantee OGIVRI coverage or reimbursement.

Sample CMS-1500 Claim Form

This sample form is provided for your information only. Please call My Biocon Biologics at 1 (833) 695-2623 with questions on coding and claim information for specific payers.

BOX 19 ADDITIONAL INFORMATION

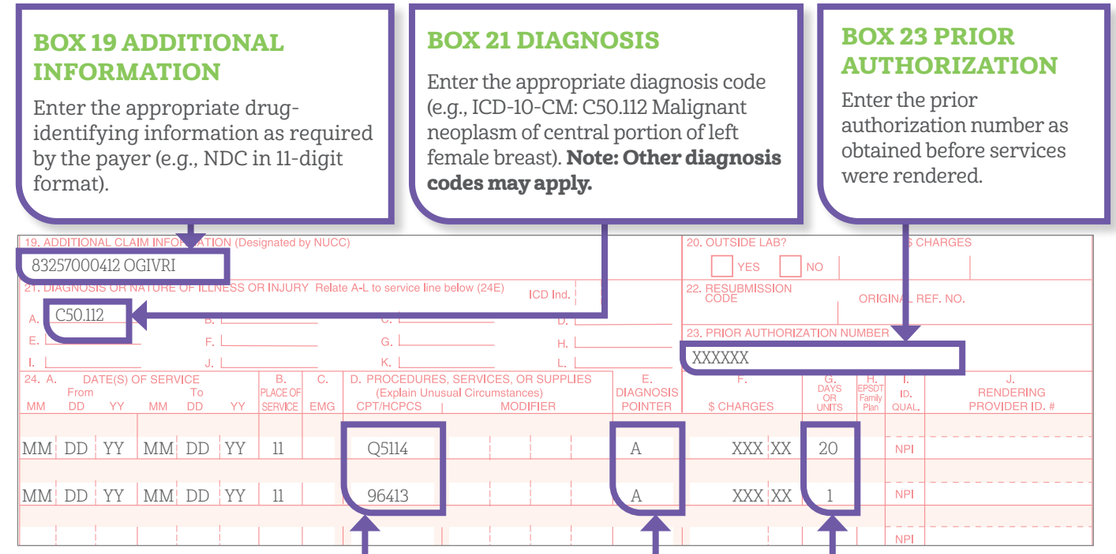
Enter the appropriate drug-identifying information as required by the payer (e.g., NDC in 11-digit format).

BOX 21 DIAGNOSIS

Enter the appropriate diagnosis code (e.g., ICD-10-CM: C50.112 Malignant neoplasm of central portion of left female breast). **Note: Other diagnosis codes may apply.**

BOX 23 PRIOR AUTHORIZATION

Enter the prior authorization number as obtained before services were rendered.



BOX 24D PROCEDURES/ SERVICES/SUPPLIES

Enter the appropriate CPT/HCPCS codes and modifiers. The treating healthcare professional must confirm the drug (e.g., Q5114 for OGIVRI) and administration (e.g., 96413 for IV administration up to 1 hour).

BOX 24E DIAGNOSIS POINTER

Enter the letter (A–L) from Box 21 for the diagnosis that corresponds to the line item.

BOX 24G UNITS

Enter the appropriate number of units of services (for illustrative purposes, Q5114 has billing units of 10 mg; for a 200 mg dose, 20 units should be billed).

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Sample CMS-1450 (UB-04) Claim Form

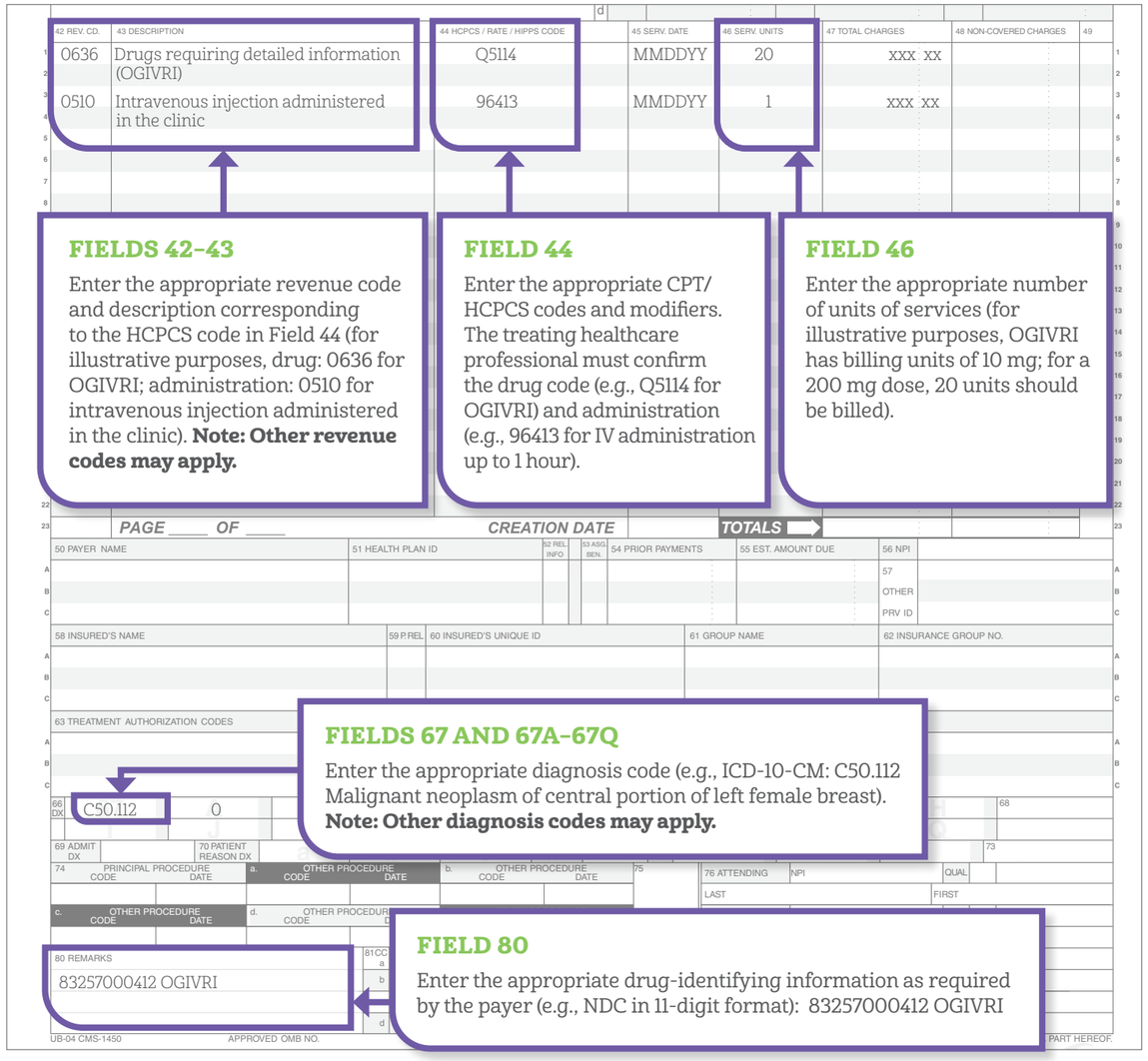
Products and services provided in the hospital outpatient facility are billed using the CMS-1450 institutional claim form or the electronic claim file (837I). This form is also referred to as UB-04. Required information includes patient demographic and insurance information, insurance policy number, codes to indicate the services and products provided to the patient, revenue codes, and the provider's NPI. Reported codes (e.g., ICD-10-CM, CPT, and HCPCS codes) must be supported by the information in the patient's medical record. Filling out an accurate and complete claim form is critical for timely processing and reimbursement of your claim. A sample CMS-1450 claim form for OGIVRI (trastuzumab-dkst) administered to a Medicare patient is provided.

Please note that information specific to coding and payment is subject to change and should be verified for each patient prior to treatment. Information presented here is current as of February 2023.

The content provided on this sample claim form is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure OGIVRI claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios and Biocon Biologics does not guarantee OGIVRI coverage or reimbursement.

Sample CMS-1450 (UB-04) Claim Form

This sample form is provided for your information only. Please call My Biocon Biologics at 1 (833) 695-2623 with questions on coding and claim information for specific payers.



Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Sample Letters

Sample Letter of Medical Necessity

Payers may request a letter of medical necessity to support coverage of OGIVRI (trastuzumab-dkst). The letter explains why the drug was medically necessary for the specific patient and may include supporting documentation (e.g., medical records, peer-reviewed literature, prescribing information, etc.). The letter may be submitted as part of a prior authorization request, in tandem with the claim form, or in response to a payer's request for additional documentation.

The following is a sample letter of medical necessity, or you may use another form or format. The letter should include patient-specific information, should be on your letterhead, and be signed by the prescriber and should be submitted to a payer to support a prior authorization request or claim for OGIVRI.

[Date]
[Contact Name] [Title]
[Name of Health Insurance Company]
[Address] [City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear [Contact's Name]:

I am writing on behalf of my patient, [name of patient], to request that [name of health insurance company] approve coverage and appropriate reimbursement associated with [name of patient]'s treatment with OGIVRI (trastuzumab-dkst), a biosimilar. OGIVRI is an FDA-approved HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Patient History and Diagnosis
[Name of patient] is a[n] [age]-year-old [male/female] born [MM-DD-YEAR] who was diagnosed on [date] for [patient's cancer diagnosis]. The patient presented with a [size] tumor located [location(s)] with involvement of [number/location of lymph nodes, if applicable]. A laboratory confirmed overexpression of HER2 protein on [date].

[Provide a brief discussion of patient's symptoms and therapy to date. Describe any surgical procedures, prior treatments, and underlying medical complications.]

Treatment Rationale and Plan
[Include FDA approval letter, relevant journal articles, clinical studies, compendia listings, and clinical practice guidelines that support the use of OGIVRI for this patient.]

The treatment plan anticipated to provide efficacious outcomes is [include dosage/length of treatment].

Based on the above facts, I am confident you will agree that OGIVRI is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [physician's telephone number (XXX) XXX-XXXX] to discuss. Thank you in advance for your prompt attention to this request.

Sincerely,

[Physician's name]
[Physician's practice name]
[Phone number]

Enclosures [supporting documentation, such as FDA approval letter and package insert, HER2 status report, pathology and surgical reports, clinical notes, CT scans and other imaging reports, additional supporting documentation, as applicable]

Please refer to the Important Safety Information, including Boxed WARNING, on pages 2–3 and 21–24. Please see accompanying full Prescribing Information, including Boxed WARNING.

Sample Appeal Letter

In some cases when a payer has denied a claim, a phone call to a payer representative may result in a denial overturn. If not, an appeal letter may be submitted in response to a payer's decision for underpayment or non-payment, as detailed in the Explanation of Benefits (EOB) or Remittance Advice. In addition to filing the appeal within timely filing limits, understanding the reasons the payer denied the claim is critical for filing a successful appeal.

The following is a sample letter of appeal, or you may use another form when submitting additional documentation to the patient's payer when appealing a denied claim for OGIVRI (trastuzumab-dkst).

[Date]
[Contact Name] [Title]
[Name of Health Insurance Company]
[Address] [City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]
Claim Control Number: [Number]

Dear [Contact's Name]:

This letter serves as a request for reconsideration for payment of a denied claim representing charges for OGIVRI (trastuzumab-dkst), a biosimilar administered to [name of patient] on [date(s) of service]. [Name of patient] is a[n] [age]-year-old [male/female] born [MM-DD-YEAR] who has been under my care for [his/her] diagnosis [patient's cancer diagnosis]. You have indicated that OGIVRI is not covered by [insurance name] because [reason for denial].

[Provide a brief discussion of patient's symptoms and therapy to date, and any other pertinent information.] Treatment with OGIVRI has resulted in [list documented outcomes] for this patient.

OGIVRI is an FDA-approved HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. OGIVRI has been administered to [name of patient] per the FDA-approved package insert dosing instructions.

OGIVRI is a medically necessary part of [name of patient]'s treatment. I request that an oncology specialist who is familiar with OGIVRI review this appeal letter with the additional enclosed documentation, as I am confident your reconsideration of this claim would yield appropriate coverage for my patient. Please contact me at [physician's telephone number (XXX) XXX-XXXX] if you require additional information.

Thank you in advance for your prompt attention to this request.

Sincerely,

[Physician's name]
[Physician's practice name]
[Phone number]

Enclosures [original claim form, denial/EOB, supporting documentation such as FDA approval letter and package insert, HER2 status report, pathology and surgical reports, clinical notes, CT scans and other imaging reports, additional supporting documentation as applicable]

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

Adjuvant Breast Cancer:

OGIVRI 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
- 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 OGIVRI.

* 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:

OGIVRI 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 OGIVRI.

Metastatic Gastric Cancer:

OGIVRI 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 OGIVRI.

IMPORTANT SAFETY INFORMATION (cont.)

WARNING: CARDIOMYOPATHY, INFUSION REACTIONS, EMBRYO-FETAL TOXICITY, and PULMONARY TOXICITY

Cardiomyopathy

Administration of OGIVRI can result in sub-clinical and clinical cardiac failure. The incidence and severity are highest in patients receiving OGIVRI with anthracycline-containing chemotherapy regimens.

Evaluate left ventricular function in all patients prior to and during treatment with OGIVRI. Discontinue OGIVRI treatment in patients receiving adjuvant therapy and withhold OGIVRI in patients with metastatic disease for clinically significant decrease in left ventricular function.

Infusion Reactions; Pulmonary Toxicity

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

Embryo-Fetal Toxicity

Exposure to OGIVRI 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

- OGIVRI administration can result in sub-clinical and clinical cardiac failure. The incidence and severity are highest in patients receiving OGIVRI with anthracycline-containing chemotherapy regimens
- OGIVRI can cause left ventricular cardiac dysfunction, arrhythmias, hypertension, disabling cardiac failure, cardiomyopathy, and cardiac death. OGIVRI can also cause asymptomatic decline in left ventricular ejection fraction (LVEF). Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan
- Evaluate left ventricular function in all patients prior to and during treatment with OGIVRI
- Discontinue OGIVRI treatment in patients receiving adjuvant therapy and withhold OGIVRI in patients with metastatic disease for clinically significant decrease in left ventricular function

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IMPORTANT SAFETY INFORMATION (cont.)

Infusion Reactions

- OGIVRI administration can result in serious and fatal infusion reactions
- Symptoms usually occur during or within 24 hours of OGIVRI administration
- Interrupt OGIVRI infusion for dyspnea or clinically significant hypotension
- Monitor patients until symptoms completely resolve
- Discontinue OGIVRI 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 OGIVRI 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 OGIVRI
- Advise pregnant women and females of reproductive potential that exposure to OGIVRI 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 OGIVRI. 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 OGIVRI treatment and any potential adverse effects on the breastfed child from OGIVRI or from the underlying maternal condition

Pulmonary Toxicity

- OGIVRI administration 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 OGIVRI 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

- **Adjuvant Breast Cancer:** Most common adverse reactions (≥ 5%) are headache, diarrhea, nausea, and chills.
- **Metastatic Breast Cancer:** Most common adverse reactions (≥ 10%) are fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
- **Metastatic Gastric Cancer:** Most common adverse reactions (≥ 10%) are neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

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