HERCESSI™
(trastuzumab-strf)
For Injection

HERCESSI™ Billing and Coding Guide

HCPCS Code: Q5146

Accord BioPharma, Inc. developed this guide to assist health care providers (HCPs) and staff on coding, billing, and reimbursement for HERCESSI™ when administered in the physician office or hospital outpatient department (HOPD).

The information in this guide is for informational purposes only. Accord BioPharma, Inc. does not guarantee reimbursement for HERCESSI. It is the sole responsibility of the HCPs to ensure the reported codes are accurate, complete, and supported by medical record documentation.

Please see Important Safety Information and Indications on pages 3-5 and for the HERCESSI full Prescribing Information including BOXED WARNINGS, visit https://www.accordbiopharma.com/our-therapies/hercessi/hercessi_pi.pdf.

HS-HER-2400001

accord™

TABLE OF CONTENTS

IMPORTANT SAFETY INFORMATION[1]

HERCESSI™ (trastuzumab-strf) for injection, for intravenous use

HERCESSI (trastuzumab-strf) is biosimilar to HERCEPTIN® (trastuzumab).

BOXED WARNING AND ADDITIONAL IMPORTANT SAFETY INFORMATION[1]

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

See full prescribing information for complete boxed warning

Cardiomyopathy: Trastuzumab products can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue HERCESSI for cardiomyopathy.

Infusion Reactions, Pulmonary Toxicity: Discontinue HERCESSI for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.

Embryo-Fetal Toxicity: Exposure to trastuzumab products during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception.

Cardiomyopathy:

- **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.**
- 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 HERCESSI treatment in patients receiving adjuvant therapy and withhold HERCESSI in patients with metastatic disease for clinically significant decrease in left ventricular function.

Cardiac Monitoring

- Evaluate left ventricular function by echocardiogram or MUGA scan in all patients prior to and every 3 months during treatment with HERCESSI, and every 6 months for at least 2 years following completion of HERCESSI as a component of adjuvant therapy.
- Repeat LVEF measurement at 4 week intervals if HERCESSI is withheld for significant left ventricular cardiac dysfunction.
- The safety of continuation or resumption of HERCESSI in patients with trastuzumab product-induced left ventricular cardiac dysfunction has not been studied.

IMPORTANT SAFETY INFORMATION *(Continued)*

Infusion Reactions

- **With trastuzumab products, serious and fatal infusion reactions have been reported.** Severe reactions, which include bronchospasm, anaphylaxis, angioedema, hypoxia, and severe hypotension were usually reported during or immediately following the initial infusion.
- Interrupt HERCESSI infusion for dyspnea, clinically significant hypotension, and intervention of medical therapy administered (which may include epinephrine, corticosteroids, diphenhydramine, bronchodilators, and oxygen).
- Monitor patients until symptoms completely resolve.
- Discontinue HERCESSI for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Strongly consider permanent discontinuation in all patients with severe infusion reactions.
- Infusion reactions consist of a symptom complex characterized by fever and chills, and on occasion include nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, dyspnea, hypotension, rash, and asthenia.

Embryo-Fetal Toxicity

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.**
- Verify the pregnancy status of females of reproductive potential prior to the initiation of HERCESSI.
- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of HERCESSI. 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 HERCESSI treatment and any potential adverse effects on the breastfed child from HERCESSI or from the underlying maternal condition. This consideration should also take into account the trastuzumab product wash out period of 7 months.

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 HERCESSI 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.

IMPORTANT SAFETY INFORMATION *(Continued)*

Most Common Adverse Reactions

- The most common adverse reactions associated with trastuzumab products in adjuvant and metastatic breast cancer are fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia. Adverse reactions requiring interruption or discontinuation of trastuzumab product treatment include CHF, significant decline in left ventricular cardiac function, severe infusion reactions, and pulmonary toxicity.
- In the metastatic gastric cancer setting, the most common adverse reactions (≥ 10%) that were increased (≥ 5% difference) in the trastuzumab arm as compared to the chemotherapy alone arm were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.
- The most common adverse reactions which resulted in discontinuation of treatment in the trastuzumab-containing arm in the absence of disease progression were infection, diarrhea, and febrile neutropenia.

INDICATIONS

Adjuvant Breast Cancer

HERCESSI™ (trastuzumab-strf) is indicated in adults for adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR-negative or with one high-risk feature) breast cancer:

- as part of a treatment regimen containing doxorubicin, cyclophosphamide and either paclitaxel or docetaxel
- as part of a treatment regimen with docetaxel and carboplatin
- as a single agent following multi-modality anthracycline-based therapy

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

Metastatic Breast Cancer

HERCESSI is indicated in adults:

- 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

HERCESSI is indicated in adults, 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.

HERCESSI™ (trastuzumab-strf) for injection is available as a single-dose vial for the 150 mg/vial strength and as a multiple-dose vial for the 420 mg/vial strength.

Click here for full Prescribing Information, including Boxed Warnings.

Herceptin® (trastuzumab) is a registered trademark of Genentech USA, Inc.

CODING AND BILLING BY SITE OF CARE

The following section provides coding and billing guidance for HERCESSI administered in a physician office or HOPD. As coding and billing requirements for HERCESSI may vary, it is important to verify individual payer policy requirements.

ICD-10-CM CODES

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

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

ICD-10-CM Code[2,3]	Description
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, C50.912, C50.919	Malignant neoplasm of breast (female)
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	Malignant neoplasm of breast (male)
C16.0-C16.6, C16.8-C16.9	Malignant neoplasm of stomach

HERCESSI Billing Units:

HERCESSI HCPCS code Q5146 is described as “Injection, trastuzumab-strf, biosimilar, (HERCESSI), 10 mg."

10 milligrams = 1 billing unit

NDCs

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

Strength[1]	Vial Size	10-Digit NDC	11-Digit NDC
420 mg/vial	420 mg lyophilized powder in a multiple-dose vial for reconstitution	69448-016-11	69448-0016-11
150 mg/vial	150 mg lyophilized powder in a single-dose vial for reconstitution	69448-015-05	69448-0015-05

The following section provides coding and billing guidance for HERCESSI administered in a physician office or HOPD. **As coding and billing requirements for HERCESSI may vary, it is important to verify individual payer policy requirements**.

HCPCS CODE

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

Effective for dates of service on and after January 1, 2025 , HCPCS code Q5146 may be used to report HERCESSI.

HCPCS Code[5]	Description
Q5146	Injection, trastuzumab-strf, biosimilar, (HERCESSI), 10 mg

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

HCPCS Modifier[6,7]	Description
JA	Intravenous administration
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

CPT® CODES

Current Procedural Terminology (CPT) codes define specific medical procedures performed by HCPs.

The following codes may be used to report the administration of HERCESSI:

Type of Code	Code/Description	Relevant Sites of Service
Administration: CPT codes[8]	**96413:** Injection and Intravenous Infusion (initial hour) Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration.	Physician office and hospital outpatient department
	96415: Chemotherapy administration, IV infusion technique; each additional hour (List separately in addition to code for primary procedure).	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour.	

REVENUE CODES:

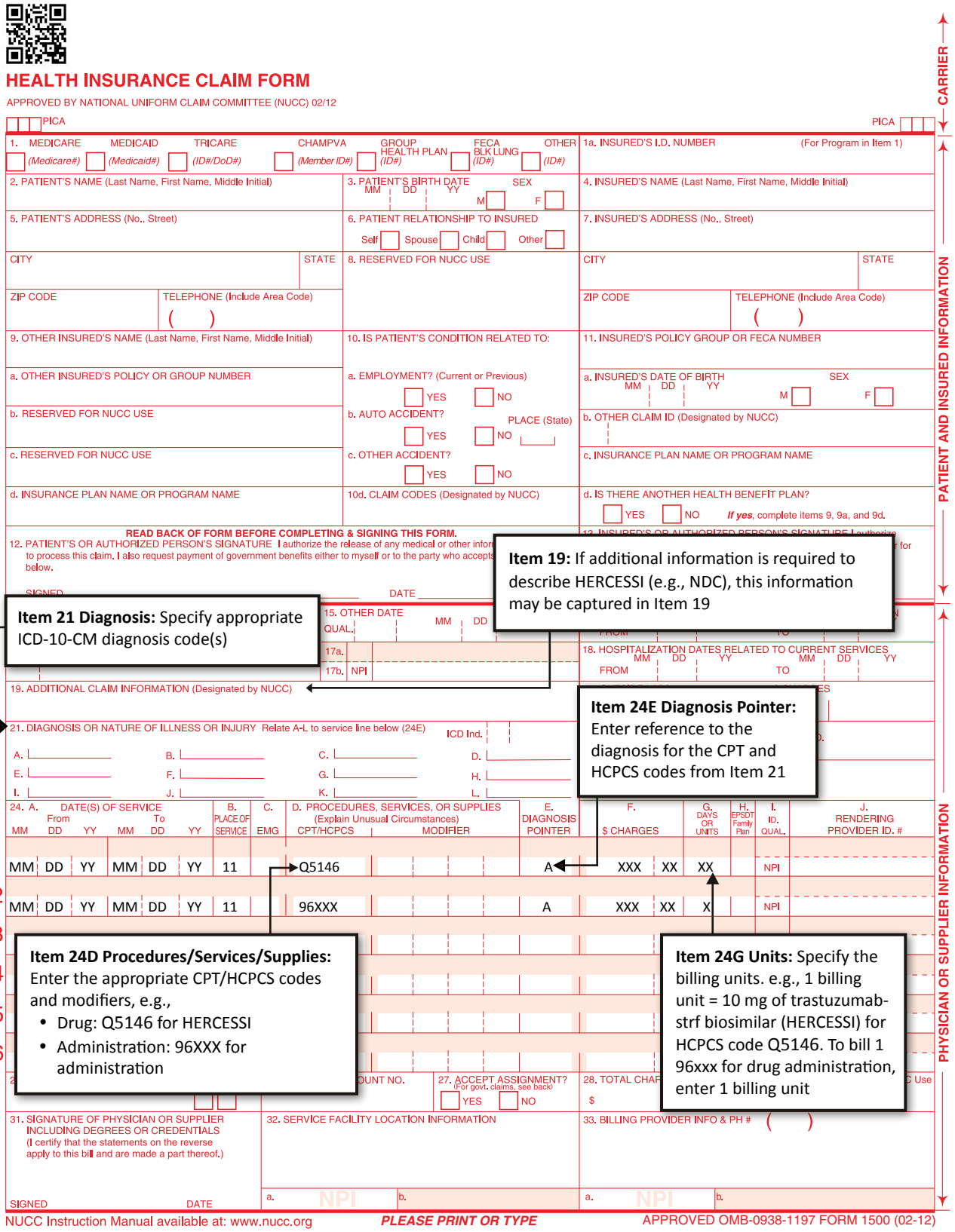
Hospital outpatient departments use revenue codes to report specific accommodations and/or ancillary charges.

Type of Code	Code/Description	Relevant Sites of Service
Revenue codes[9]	**0636:** Drugs requiring detailed coding	Hospital outpatient department
	0500: Outpatient services – general classification	
	0510: Clinic – general classification	

Key: IV – intravenous

SAMPLE CLAIM FORM

SAMPLE PHYSICIAN OFFICE (CMS-1500) CLAIM FORM[10]



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other infor... to process this claim. I also request payment of government benefits either to myself or to the party who accepts ... below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize ... for

15. OTHER DATE QUAL. MM DD

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.
E. F. G. H.
I. J. K. L.

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		Q5146		A	XXX	XX	XX		NPI
2 MM DD YY	MM DD YY	11		96XXX		A	XXX	XX	X		NPI
3											
4											
5											
6											

2 ...OUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO 28. TOTAL CHAR... $ ...C Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 19: If additional information is required to describe HERCESSI (e.g., NDC), this information may be captured in Item 19

Item 21 Diagnosis: Specify appropriate ICD-10-CM diagnosis code(s)

Item 24E Diagnosis Pointer: Enter reference to the diagnosis for the CPT and HCPCS codes from Item 21

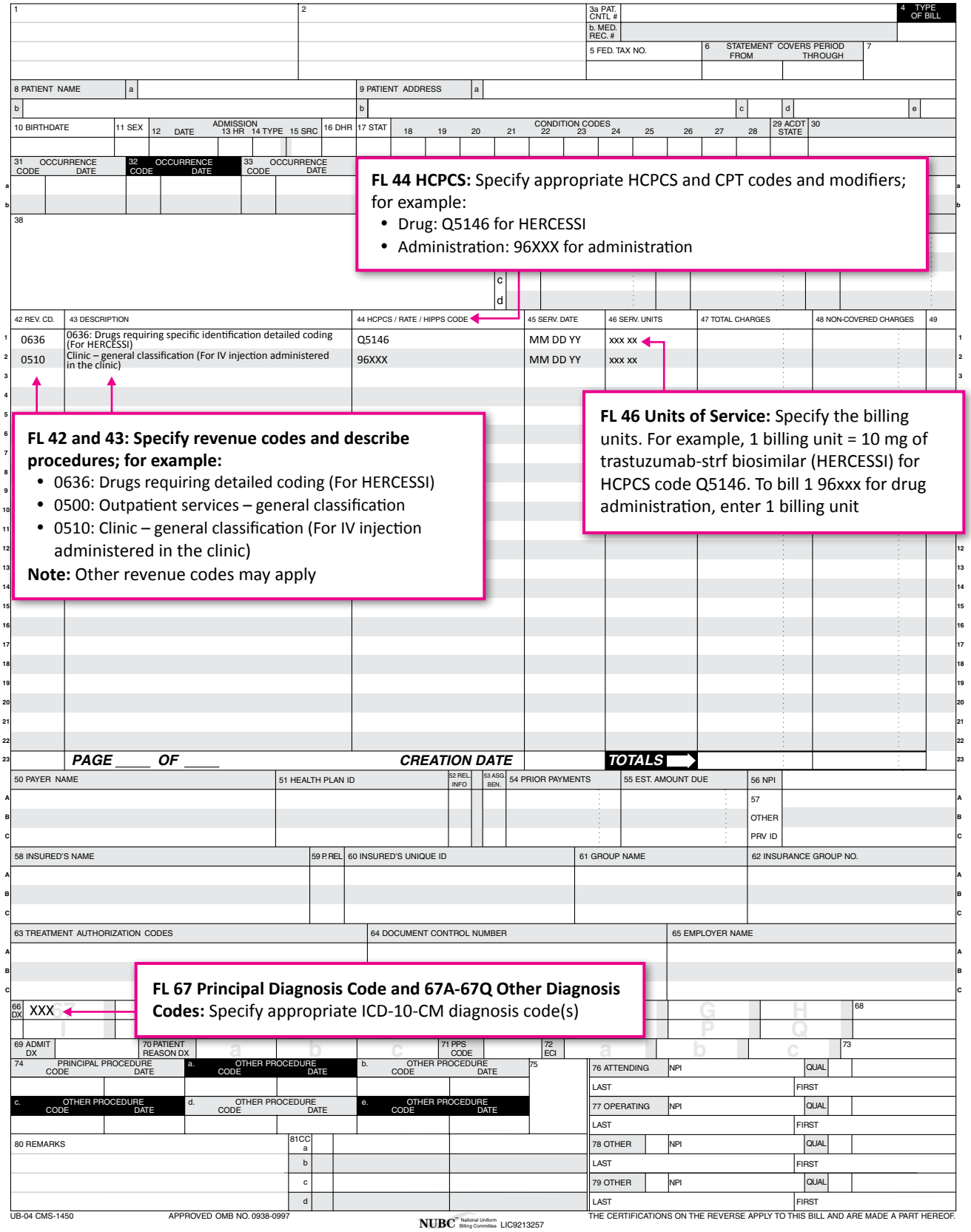
Item 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, e.g.,

- Drug: Q5146 for HERCESSI
- Administration: 96XXX for administration

Item 24G Units: Specify the billing units. e.g., 1 billing unit = 10 mg of trastuzumab-strf biosimilar (HERCESSI) for HCPCS code Q5146. To bill 1 96xxx for drug administration, enter 1 billing unit

SAMPLE CLAIM FORM

SAMPLE HERCESSI HOPD (CMS-1450 [UB-04]) CLAIM FORM[11]



ACCORDCARES® PATIENT SUPPORT SERVICES

Accord BioPharma is committed to helping patients gain access to the medicines they need. Key offerings available for eligible patients through the AccordCares® program include:

- Co-pay Assistance
- Patient Assistance
- Benefits Investigation
- Prior Authorization
- Billing and Coding Information
- Alternate Coverage Identification

An AccordCares® associate can be reached Monday through Friday 8 AM to 8 PM ET at:

- **PHONE:** 1-866-258-7151
- **FAX:** 1-855-558-6304
- Or by **mail** at PO Box 4485 Chesterfield, MO 63006

REFERENCES

1. HERCESSI Prescribing Information. Accord BioPharma, Inc.; Issued September 2024.

2. 2025 ICD-10-CM Codes C50*: Malignant neoplasm of breast. Accessed November 15, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C50-C50/C50-#:~:text=*%20C50.011%20Malignant%20neoplasm%20of%20nipple%20and,of%20nipple%20and%20areola%2C%20unspecified%20female%20breast.

3. 2025 ICD-10-CM Codes C16*: Malignant neoplasm of stomach. Accessed November 15, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C15-C26/C16-#:~:text=A%20type%202%20excludes%20note,Malignant%20neoplasm%20of%20stomach%2C%20unspecified.

4. Future Format of the National Drug Code; Public Hearing; Request for Comments. Fed Regist. 2018;82(152):38666-38669. To be codified at 21 CFR 15. October 10, 2023. https://www.govinfo.gov/content/pkg/FR-2018-08-07/pdf/2018-16807.pdf.

5. Centers for Medicare & Medicaid Services. (2024). Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations: Third Quarter, 2024 HCPCS Coding Cycle. Retrieved from https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals-posted-10-02-2024.pdf.

6. Centers for Medicare & Medicaid Services. The use of the JA and JG modifiers for claims with the subcutaneous injection of the drug. Medicare Coverage Database. Retrieved September 16, 2024, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527&ver=33.

7. Centers for Medicare & Medicaid Services (CMS). Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed September 16, 2024. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

8. AAPC. CPT codes range. AAPC. Retrieved September 16, 2024, from https://www.aapc.com/codes/cpt-codes-range/.

9. Noridian Healthcare Solutions. Revenue codes. Accessed May 21, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes.

10. Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Accessed September 16, 2024. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-1500and1490s.

11. Centers for Medicare & Medicaid Services. CMS-1450: Medicare Uniform Instructional Provider Bill and Supporting Regulations. July 19, 2019. Accessed September 16, 2024. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-1450.