



Margenza[®]

(margetuximab-cmkb)

250 mg/10 mL injection for intravenous use

Billing and Coding Guide

INDICATION

MARGENZA is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

SELECT SAFETY INFORMATION

BOXED WARNING: LEFT VENTRICULAR DYSFUNCTION AND EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction:** MARGENZA may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate cardiac function prior to and during treatment. Discontinue MARGENZA treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-Fetal Toxicity:** Exposure to MARGENZA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

Please see Full Important Safety Information on page 7 and accompanying [Full Prescribing Information](#), including BOXED WARNING.

TerSera Therapeutics has created this guide to assist healthcare professionals (HCPs) in obtaining insurance reimbursement for MARGENZA® (margetuximab-cmkb)

Disclaimer: Third-party reimbursement is affected by many factors. This document and the information and assistance provided by TerSera or TerSera SupportSource are presented for informational purposes only. They do not constitute reimbursement or legal advice. TerSera does not promise or guarantee coverage, levels of reimbursement, or payment. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Accordingly, the information may not be current or comprehensive. TerSera and its third-party service providers strongly recommend you consult your payer for its most current coverage, reimbursement, and medical policies. TerSera and its third-party service providers make no representations or warranties, expressed or implied, as to the accuracy of the information provided. In no event shall the third-party service providers or TerSera, or their employees or agents, be liable for any damages resulting from or relating to any information provided by, or accessed to or through, TerSera or TerSera SupportSource. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions specific to your institution.



TerSera SupportSource for MARGENZA provides support to help patients access treatment

- Helps you understand what financial support may be available through independent assistance foundations
- Eligible commercially insured patients may reduce out-of-pocket MARGENZA prescription costs with the MARGENZA Co-pay Savings Program*
- Offers the Patient Assistance Program to eligible patients with established financial need to receive free product. Terms and conditions apply

*For eligible commercially insured patients, the co-pay card is subject to an annual limit. Customers are not eligible if prescriptions are paid for by any state or other federally funded programs, including, but not limited to, Medicare or Medicaid, VA, DOD, TRICARE, or where prohibited by law. Additional terms and conditions apply.



Scan to visit MargenzaSupport.com
or call 1-833-377-HER2 (4372)

Please see [Full Important Safety Information](#) on page 7 and accompanying [Full Prescribing Information](#), including **BOXED WARNING**.



Potential Billing Codes for MARGENZA® (margetuximab-cmkb)

Code Type	Codes		Category of Treatment or Description
ICD-10-CM Diagnosis Codes ¹	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 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 male breast
Permanent HCPCS J-code ²	J9353		Injection, margetuximab-cmkb, 5 mg
National Drug Codes	10-digit NDC ³	11-digit NDC ^{3,4}	
	74527-022-02	74527-0022-02	One (250 mg/10 mL) single-dose vial
	74527-022-03	74527-0022-03	Four (250 mg/10 mL) single-dose vials
CPT® Procedure Codes 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 (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 (list separately in addition to code for primary procedure)
AHA Revenue Codes ⁶	0335		Chemotherapy administration, intravenous
	0636		Drugs requiring detailed coding
	0250		Pharmacy, general
	0260		Intravenous therapy, general

Healthcare Common Procedure Coding System (HCPCS)

Modifiers	Modifier Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

Special Note: The place of service codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payers (eg, Medicare, Medicaid, other private insurance) for reimbursement policies regarding these codes. Place of Service 11 refers to an office location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.

CPT® is a registered trademark of the American Medical Association.

AHA=American Hospital Association; CPT®=Current Procedural Terminology®; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

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Sample CMS-1500 Claim Form – Physician’s Office Setting⁷

The CMS-1500 Claim Form is used to bill for products and services administered in a physician’s office.⁸ Below is a sample CMS-1500 Claim Form as a reference on how a form may be completed for MARGENZA® (margetuximab-cmkb).

A 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

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

C 24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPISODE Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

D **E** **F**

20. OUTSIDE LAB? YES NO \$ CHARGES

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For group, clients, or school) YES NO 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rsvd for NUCC Use

PHYSICIAN OR SUPPLIER INFORMATION

For illustrative purposes only. All coding and documentation requirements should be confirmed with each health plan.

A Item 19

Health plans may require inclusion of MARGENZA, route of administration (infusion), NDC, and total dosage. Check with the health plan to verify requirements.

B Item 21

Insert the appropriate ICD-10-CM diagnosis code.

C Item 24A-B

Insert the date of infusion administration and the applicable place of service code.

D Item 24D

Insert the permanent HCPCS J-code for MARGENZA (J9353)² and CPT® code(s) for infusion administration.

E Item 24E

Insert the ICD-10-CM diagnosis code reference letter, as shown in Item 21, to relate MARGENZA and infusion administration listed in Box 24D.

F Item 24G

Insert the number of billing units for each line item. For example, 1 billing unit = 5 mg of MARGENZA. Actual units reported will be determined by the dosage amount required for each individual patient. Use the JW modifier to report any discarded drug units from a single-use vial, as required by Medicare and other health plans. Use the JZ modifier to indicate that no drug was discarded from the single-use vial. This modifier is required when the entire vial is administered to the patient.

Please see Full Important Safety Information on page 7 and accompanying Full Prescribing Information, including BOXED WARNING.

Sample CMS-1450 (UB-04) Claim Form – Institutional or Hospital Setting⁹

The CMS-1450 (UB-04) Claim Form is used for submitting institutional claims for inpatient and outpatient services.¹⁰ Below is a sample CMS-1450 (UB-04) Claim Form as a reference on how a form may be completed for MARGENZA® (margetuximab-cmkb).

A		B		C		D		E	
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1									1
2									2
3									3
4									4
5									5
6									6

A Form Locator (FL) 42
Insert applicable AHA revenue codes.

B FL 43
Insert a description for the AHA revenue code listed in FL 42.

C FL 44
Insert the permanent HCPCS J-code for MARGENZA (J9353)² and CPT® code(s) for infusion administration.

D FL 45
Insert the date of infusion administration.

E FL 46
Insert the number of billing units for each line item. For example, 1 billing unit = 5 mg of MARGENZA. Actual units reported will be determined by the dosage amount required for each individual patient. Use the JW modifier to report any discarded drug units from a single-use vial, as required by Medicare and other health plans. Use the JZ modifier to indicate that no drug was discarded from the single-use vial. This modifier is required when the entire vial is administered to the patient.

F		A		B		C		D		E		F		G		H							
66 DX	67	J	K	L	M	N	O	P	Q	76 ATTENDING	NPI	QUAL	77 OPERATING	NPI	QUAL	78 OTHER	NPI	QUAL	79 OTHER	NPI	QUAL		
66	67																						
69 ADMIT DX	70 PATIENT REASON DX	a.	b.	c.	d.	e.	f.	71 PPS CODE	72 ECI	LAST	FIRST		LAST	FIRST		LAST	FIRST		LAST	FIRST			
74 PRINCIPAL PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE																
c.	DATE	d.	DATE	e.	DATE	OTHER PROCEDURE CODE	DATE																
80 REMARKS			81CC a			b			c			d											

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

For illustrative purposes only. All coding and documentation requirements should be confirmed with each health plan.

F FL 67
Insert the appropriate ICD-10-CM diagnosis code.

G FL 80
Health plans may require inclusion of MARGENZA, route of administration (infusion), NDC, and total dosage. Check with the health plan to verify requirements.

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To order MARGENZA, contact these authorized distributors directly:

Authorized distributor	Phone number
ASD Healthcare	800-746-6273
Cardinal Health Specialty Distribution	877-453-3072
McKesson Plasma and Biologics	877-599-7748
McKesson Specialty Care Distribution	800-482-6700
Oncology Supply	800-633-7555

Dosing and administration³

- MARGENZA injection is a clear to slightly opalescent, colorless to pale yellow or pale brown solution in a single-dose vial
- The recommended dose of MARGENZA is 15 mg/kg, administered as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity
- Administer MARGENZA as an intravenous infusion at 15 mg/kg over 120 minutes for the initial dose, then over a minimum of 30 minutes every 3 weeks for all subsequent doses
- On days when both MARGENZA and chemotherapy are to be administered, MARGENZA may be administered immediately after chemotherapy completion
- Refer to the respective Prescribing Information for each therapeutic agent administered in combination with MARGENZA for the recommended dosage information, as appropriate



1- and 4-pack options available

For illustration purposes only.

Storage and handling³

- Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light until time of use. **Do not freeze. Do not shake**

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INDICATION

MARGENZA is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: LEFT VENTRICULAR DYSFUNCTION AND EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction:** MARGENZA may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate cardiac function prior to and during treatment. Discontinue MARGENZA treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-Fetal Toxicity:** Exposure to MARGENZA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Left Ventricular Dysfunction

- Evaluate cardiac function within 4 weeks prior to and every 3 months during and upon completion of treatment.
- In the pivotal SOPHIA study, left ventricular dysfunction occurred in 1.9% of patients treated with MARGENZA.
- MARGENZA has not been studied in patients with a pretreatment LVEF value of <50%, a prior history of myocardial infarction, or unstable angina within 6 months, or congestive heart failure NYHA class II-IV.

Embryo-Fetal Toxicity

- Based on findings in animals and mechanism of action, MARGENZA can cause fetal harm when administered to a pregnant woman.
- Verify pregnancy status of women of reproductive potential prior to initiation of MARGENZA.

Infusion-Related Reactions (IRRs)

- MARGENZA can cause IRRs. Monitor patients during and after MARGENZA infusion for signs and symptoms. If a significant infusion-associated reaction occurs, slow or interrupt the infusion and administer appropriate medical therapies.
- In the pivotal SOPHIA study, IRRs were reported by 13% of patients on MARGENZA plus chemotherapy. Most of the IRRs occur during Cycle 1. Grade 3 IRRs were reported in 1.5% of MARGENZA-treated patients.
- Interrupt MARGENZA infusion in patients experiencing dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve.

MOST COMMON ADVERSE REACTIONS

The most common adverse drug reactions (>10%) with MARGENZA in combination with chemotherapy in order of frequency are fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

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References:

1. Centers for Medicare and Medicare Services. ICD-10 Code Lookup. Accessed September 10, 2025. <https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx>.
2. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions First Quarter 2021 Coding Cycle for Drug and Biological Products. Accessed September 10, 2025. <https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-1-2021-drugs-and-biologics.pdf>.
3. MARGENZA® (margetuximab-cmkb). Prescribing Information. TerSera Therapeutics LLC.
4. Federal Register. Future Format of the National Drug Code; Public Hearing; Request for Comments. Vol 83, No. 152. Published August 7, 2018. Accessed September 10, 2025. <https://www.govinfo.gov/content/pkg/FR-2018-08-07/pdf/2018-16807.pdf>.
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6. Centers for Medicare & Medicaid Services. Medicare Intermediary Manual. Transmittal 1875. Published February 7, 2003. Accessed September 10, 2025. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File.html>.
7. Centers for Medicare & Medicaid Services. CMS forms. Accessed September 10, 2025. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf>.
8. Centers for Medicare & Medicaid Services. Professional paper claim form (CMS-1500). Accessed September 10, 2025. <https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/1500>.
9. Centers for Medicare & Medicaid Services. CMS forms. Accessed September 10, 2025. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450>.
10. Centers for Medicare & Medicaid Services. Professional paper claim form (CMS-1450). Accessed September 10, 2025. https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/15_1450.