



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.

IMPORTANT SAFETY INFORMATION

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.

HER2=human epidermal growth factor receptor 2.

Please see Important Safety Information on pages 6-7, and full [Prescribing Information](#), including Boxed Warning.

Introduction

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

MacroGenics has identified the potential billing codes listed on the next page to assist HCPs with obtaining insurance reimbursement for MARGENZA and its administration. **Please note that coverage, coding, and payment may vary significantly by patient, payer, plan, treatment setting, and site of care. MacroGenics makes no representation, warranty, or guarantee that the information provided herein is up to date and/or accurate, will satisfy the requirements of the patient's insurer or payer, or result in payment. All codes included in this guide are for informational purposes only and do not guarantee payment of any claim. It is the sole responsibility of HCPs to select the appropriate codes and ensure the accuracy of all claims submitted for reimbursement.**

MARGENZA Patient Support is here to help

Healthcare providers and prescribers can call **1-844-MED-MGNX** to speak with a Case Manager who can assist with:

- Ordering information
- Billing and coding assistance
- Reimbursement support
- Patient Assistance Program and Copay Assistance Program details



Case Managers are available Monday-Friday, 9 AM to 7 PM ET.

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,a}	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

^aEffective for dates of service on or after July 1, 2021.

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

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

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 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 discarded units as required by Medicare or other health plans.

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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		

66 DX	67	68
69 ADMIT DX	70 PATIENT REASON	71 PPS CODE
74 PRINCIPAL PROCEDURE CODE	75	76 ATTENDING NPI
77 OPERATING NPI	78 OTHER NPI	79 OTHER NPI
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.

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

D FL 45
Insert the date of infusion administration.

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

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 discarded units as required by Medicare or other health plans.

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

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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WARNINGS & PRECAUTIONS:

Left Ventricular Dysfunction

- Left ventricular cardiac dysfunction can occur with MARGENZA.
- In SOPHIA, 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.
- Withhold MARGENZA for $\geq 16\%$ absolute decrease in LVEF from pretreatment values or LVEF below institutional limits of normal (or 50% if no limits available) and $\geq 10\%$ absolute decrease in LVEF from pretreatment values.
- Permanently discontinue MARGENZA if LVEF decline persists greater than 8 weeks, or dosing is interrupted more than 3 times due to LVEF decline.
- Evaluate cardiac function within 4 weeks prior to and every 3 months during and upon completion of treatment. Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.
- Monitor cardiac function every 4 weeks if MARGENZA is withheld for significant left ventricular cardiac dysfunction.

Embryo-Fetal Toxicity

- Based on findings in animals and mechanism of action, MARGENZA can cause fetal harm when administered to a pregnant woman. Post-marketing studies of other HER2 directed antibodies during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.
- Verify pregnancy status of women of reproductive potential prior to initiation of MARGENZA.
- Advise pregnant women and women of reproductive potential that exposure to MARGENZA during pregnancy or within 4 months prior to conception can result in fetal harm.
- Advise women of reproductive potential to use effective contraception during treatment and for 4 months following the last dose of MARGENZA.

Important Safety Information (cont'd)

Infusion-Related Reactions (IRRs)

- MARGENZA can cause IRRs. Symptoms may include fever, chills, arthralgia, cough, dizziness, fatigue, nausea, vomiting, headache, diaphoresis, tachycardia, hypotension, pruritus, rash, urticaria, and dyspnea.
- In SOPHIA, 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.
- Monitor patients during and after MARGENZA infusion. Have medications and emergency equipment to treat IRRs available for immediate use.
- In patients experiencing mild or moderate IRRs, decrease rate of infusion and consider premedications, including antihistamines, corticosteroids, and antipyretics. Monitor patients until symptoms completely resolve.
- Interrupt MARGENZA infusion in patients experiencing dyspnea or clinically significant hypotension and intervene with supportive medical therapy as needed. Permanently discontinue MARGENZA in all patients with severe or life-threatening IRRs.

MOST COMMON ADVERSE REACTIONS:

The most common adverse drug reactions (>10%) with MARGENZA in combination with chemotherapy are fatigue/asthenia (57%), nausea (33%), diarrhea (25%), vomiting (21%), constipation (19%), headache (19%), pyrexia (19%), alopecia (18%), abdominal pain (17%), peripheral neuropathy (16%), arthralgia/myalgia (14%), cough (14%), decreased appetite (14%), dyspnea (13%), infusion-related reactions (13%), palmar-plantar erythrodysesthesia (13%), and extremity pain (11%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to MacroGenics at (844)-MED-MGNX (844-633-6469).

Please see full Prescribing Information, including Boxed Warning.

References:

1. Centers for Medicare and Medicaid Services. ICD-10 Code Lookup. Accessed May 20, 2021. <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 May 21, 2021. <https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-1-2021-drugs-and-biologics.pdf>.
3. MARGENZA Prescribing Information. MacroGenics, Inc; 2020.
4. Federal Register. Future Format of the National Drug Code; Public Hearing; Request for Comments. Vol 83, No. 152. Published August 7, 2018. Accessed May 20, 2021. <https://www.govinfo.gov/content/pkg/FR-2018-08-07/pdf/2018-16807.pdf>.
5. Synovec MS, Brin KP, Jagmin CL, et al, eds. CPT 2020 Professional Edition. Chicago, IL: American Medical Association; 2019.
6. Centers for Medicare & Medicaid Services. Medicare Intermediary Manual. Transmittal 1875. Published February 7, 2003. Accessed May 20, 2021. <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 May 21, 2021. <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 May 21, 2021. <https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/1500>.
9. Centers for Medicare & Medicaid Services. CMS forms. Accessed May 21, 2021. <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 May 21, 2021. https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/15_1450.