Margenza™ (margetuximab-cmkb) 250 mg/10 mL injection for intravenous use | Patient Support Program

Patient Support Program Enrollment Form and Patient Assistance Program

MARGENZA Patient Support offers a Patient Assistance Program ("PAP") to help qualifying patients obtain MARGENZA at no cost.

This enrollment form is for patients who have been prescribed MARGENZA and would like to apply to receive the medication free of charge if they qualify.

The MARGENZA Patient Support Program, including the PAP, is not health insurance or a benefit plan. MacroGenics, Inc. ("MacroGenics") reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted. Please carefully read all Terms and Conditions on page 3 of this form.

Patients must meet all the requirements listed below to qualify (Review each item to make sure):

- **You have been prescribed MARGENZA for an FDA-approved indication**
- **You are a permanent, legal resident of the United States, Puerto Rico, or U.S. Virgin Islands**
- **You have no insurance or your insurance does not cover MARGENZA (except for Medicare beneficiaries, subject to certain restrictions). The treatment must be provided in an outpatient setting**
- **You must have received treatment within 180 days of application approval**
- **Your Annual Household Income must be at or below 400% of the Federal Poverty Guidelines. Visit https://aspe.hhs.gov/poverty-guidelines for information on the Federal Poverty Guidelines (See chart below)**

Total Number of Persons in Your Household (including applicant)	Annual Adjusted Gross Income Limit As of January 2021. Also, if you live in Alaska or Hawaii, please contact us for different annual adjusted gross income limits.
1	$51,040
2	$68,690
3	$86,880
4	$104,800
5	$122,720
6	$140,640

Application Form Instructions: Important - the entire application must be completed

Patient instructions:

- Complete the Patient Section on page 2; include appropriate documentation about patient's income
- Sign the Patient Agreement and Consent on page 2
- Sign the HIPAA Authorization on page 4

Prescriber instructions:

- Complete the Prescriber Section on pages 5-6
- The prescriber must manually sign the Prescriber Information on page 5 and the Prescriber Acknowledgment on page 6. Rubber stamps, signature by other office personnel for the prescriber, and computer-generated signatures will not be accepted

Submit the application

- **Fax the completed application and any supporting documents to MARGENZA Patient Support at 1-844-256-5226**
- Please make sure all information is provided correctly and signatures are obtained; incomplete or incorrect information will delay the process

Please see Important Safety Information on page 7 and visit www.margenza.com for full Prescribing Information, including Boxed Warning.

Hours of Operation:
Monday-Friday
9 AM to 7 PM ET

Address:
MARGENZA Patient Support Program
PO Box 3795
Chesterfield, MO 63006

Phone: 1-844-MED-MGNX
Fax: 1-844-256-5226
http://www.margenza.com

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Patient Section

All fields are required. Please print.

Patient Name (First, MI, Last) ____________________

Date of Birth (MM/DD/YYYY) ____________________ Gender ☐ Male ☐ Female

Address ____________________

City ____________________ State __________ Zip __________

Preferred Contact Method: ☐ Mobile Phone ☐ Home Phone ☐ Text   Best Time to Call: ☐ Morning ☐ Afternoon ☐ Evening

Mobile Phone #: __________ Home Phone #: __________ Email: __________

Preferred Language ☐ English ☐ Spanish ☐ Other __________

Do you have insurance? (check all that apply)		
☐ Medicaid	☐ Medicare Part B with supplemental insurance*	☐ VA or Military
☐ Medicare Part D	☐ Medicare Part B without supplemental insurance*	☐ Private Insurance†
☐ None	☐ Other: __________	

*For example, Medigap, Medicare Advantage.
†For example, employer sponsored plan, Health Insurance Marketplace plan.

Patient Insurance Information

Policy Holder Name ____________________

Group # ____________________ Policy ID # ____________________

If you checked that you have Medicare, you agree to the following when signing the Patient Agreement and Consent on the bottom of this page.

If you are a member of a Medicare plan including a Medicare Prescription Drug Plan and are qualified for program assistance, you will: (i) be eligible to obtain the medication from the program for a calendar year term; (ii) not purchase this medication under your Medicare plan while enrolled in the program; (iii) not submit claims nor seek true out-of-pocket (TrOOP) credit for the medication provided during your enrollment; (iv) certify that you are not eligible for or enrolled in Low Income Subsidy (LIS) for Medicare Part D, and have spent at least 3% of your annual household income on prescription medicines in the current year; and (v) provide written notification to your Medicare Prescription Drug Plan, if applicable, that you are receiving your medication at no cost outside of the Medicare Part D benefit.

Patient Income Information

Annual Household Adjusted Gross Income: ____________________

Total Number of People in Household (including applicant): ____________________

Authorization to Speak With Authorized Representative (Optional)

You may provide the names of one or more people with whom you authorize MARGENZA Patient Support to speak to on your behalf about this application or your participation in the MARGENZA Patient Support Program. These individuals can provide or receive your personal information as necessary until you terminate their authority. Their authority will not automatically terminate once we process your application. Their authority will terminate at the end of your enrollment period. By providing the name(s) below, you certify that individuals are aware and agree that you will provide their name to MARGENZA Patient Support for the purpose of serving as your authorized representative. You can remove Authorized Representative(s) at any time by calling MARGENZA Patient Support at 1-844-MED-MGNX.

Print Name(s) of Authorized Representative ____________________

Relationship to Patient ____________________ **Date (MM/DD/YYYY)** __________

☐ **I would like to apply to enroll in the MARGENZA Patient Assistance Program and agree to the Terms and Conditions on page 3.**

Signature of Patient ____________________ **Date (MM/DD/YYYY)** __________

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MARGENZA Patient Support Program and Patient Assistance Program Terms and Conditions

MARGENZA Patient Support offers a Patient Assistance Program ("PAP") to help qualifying patients obtain MARGENZA at no cost. The MARGENZA Patient Support Program, including the PAP, is not health insurance or a benefit plan. MacroGenics reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted. I understand that I am not required to sign these authorization forms or participate in the MARGENZA Patient Support Program and PAP. If I refuse, my eligibility for benefits under my insurance and the treatment by my healthcare provider will not change, although I will not be enrolled in the Program. This program cannot be combined with any coupon, certificate, voucher, or similar offer. **Receiving a free supply of the drug is not contingent on any future purchases of the drug or other products manufactured or marketed by MacroGenics**.

I certify (agree) that the following statements are true:

- I am 18 years of age or older and receiving MARGENZA for an FDA-approved use. (Please ask your doctor for information about FDA-approved uses. Also see your doctor for the full U.S. Prescribing Information for MARGENZA)
- I have been prescribed MARGENZA
- The treatment is provided in an outpatient setting
- I must receive treatment within 180 days of application approval, if granted
- My Annual Household Income is at or below 400% of the Federal Poverty Guidelines (Please see Annual Adjusted Gross Income Limit grid on page 1)
- I am a permanent, legal resident of the United States, Puerto Rico, or U.S. Virgin Islands
- I have no insurance or my insurance does not cover MARGENZA and am not eligible for other public health insurance programs other than Medicare Part D. If I have Medicare Part D, I agree to the following additional conditions:
    1. If I, as a Part D beneficiary of public health insurance, receive a free supply of MARGENZA under the PAP, I understand that the PAP will notify my Part D plan sponsor that the drug is being provided outside of the Part D benefit
    2. I will not seek reimbursement from my plan sponsor for any medication dispensed from the program
    3. No part of the costs of the drug provided under the PAP should be counted toward the patient's true out-of-pocket ("TrOOP") costs, and no claim should be submitted to the Part D plan sponsor for the free supply of the drug
    4. If I am a Part D beneficiary, I am not eligible for or enrolled in Low Income Subsidy (LIS) for Medicare Part D, and I have spent at least 3% of my annual household income on prescription medicines in the current year
    5. If I choose to stay on the drug after receiving the free supply or supplies (or beneficiaries who do not qualify for the Free Supply Program, and thus never receive a free supply), I may be responsible for substantial cost-sharing amounts

I understand and agree that the PAP does not provide free medicine in the instance of an administrative error or a coverage restriction such as a step edit. Some exceptions may apply. I am not receiving any other assistance to pay for my MARGENZA medication.

I consent to the sharing, use, and receipt of information about me: I understand that I or my doctor's office is submitting this application to see if I qualify for assistance with MARGENZA through MARGENZA Patient Support. I understand that before MARGENZA Patient Support can assist me, MARGENZA Patient Support may need to collect, use, and share information about me. This information is requested in this application. This information is called My Personal Information. It includes: My Protected Health Information (PHI) as defined on page 4, my financial information, and other personal information about me. I agree to allow MacroGenics to use my demographic information, including but not limited to Social Security number, date of birth, name, and/or address as needed to access my credit information and information derived from public and other sources, including information from a consumer reporting agency (credit bureau), to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility under the PAP. MacroGenics reserves the right to ask for additional documents and information at any time.

I agree to notify MARGENZA Patient Support of changes to my income or insurance status, or my status as a resident of the United States that may impact my eligibility for MARGENZA Patient Support.

MacroGenics reserves the right to modify or discontinue the PAP at any time without notice and to verify the accuracy of information submitted. Void where taxed, restricted, or prohibited by law. This offer is not transferable and is limited to one offer per person. Not valid if reproduced.

Privacy Notice and Consent to Contact by Phone or Text:

The MARGENZA Patient Support Program is governed by the MacroGenics Privacy Policy. For more information, please visit www.MacroGenics.com/privacy/.

By enrolling in the MARGENZA Patient Assistance Program, I agree to receive non-marketing calls and texts by or on behalf of MacroGenics, including through an autodialer or prerecorded voice, at the number(s) I provided. If I have provided a caregiver phone number, I certify on my caregiver's behalf that my caregiver has agreed to receive these calls and texts. Message and data rates may apply. Recurring texts; reply STOP to end texts.

Please see Important Safety Information on page 7 and visit www.margenza.com for full Prescribing Information, including Boxed Warning.

Patient HIPAA Authorization

Before MARGENZA Patient Support can start helping you, we will need some information about you and your health. This is known as your Protected Health Information, or PHI. By signing this form, you understand and agree that your PHI may be shared with and used by MacroGenics, as explained below.

PHI includes information like:

- Your health insurance or benefits, including how much coverage you have
- All records about your treatment
- Whether you're staying on your medicine or treatment
- Anything that affects your health

If you agree, your PHI may be shared by your doctors and other healthcare providers, your healthcare plan or health insurance company, clearinghouses or other agents, your pharmacy, and others who might have your PHI.

Your PHI is used for the following purposes:

- To learn how much of your treatment is covered by your insurance
- To help you find other ways to afford your treatment
- To track your use of your treatment
- To share information with your healthcare provider
- To make sure that you receive high-quality services from the program
- To measure program performance and make program improvements

Other things you should know about sharing and using your PHI:

- We only ask for and share the PHI that we need to provide the copay assistance you have requested and the optional Patient Support Services if you have requested those. We do not ask for any PHI that we do not need, but we may receive some in the health records sent to us. Your PHI will be released to MacroGenics and its affiliates, agents, representatives, and service providers
- You don't have to give permission to share your PHI with MacroGenics to receive treatment from your healthcare providers, your prescription from your pharmacy, or benefits from your healthcare plan, but MARGENZA Patient Support may not be able to help you without it
- After your PHI has been shared, it may no longer be covered by federal and state privacy laws (such as HIPAA), and it may be shared again
- Your signed permission to share and use your PHI lasts for three years from the date of your signature unless you are a resident of Maryland, Maine, or Montana, in which case the permission will last for one year from the date of your signature. In either case, you may revoke your permission before then by writing to MARGENZA Patient Support, PO Box 3795, Chesterfield, MO 63006, which will preclude reliance on the authorization after the date your written revocation is received, **although it will not affect disclosures made before your revocation is received. You have the right to receive a copy of this form**

If you would like to opt out of the program or make changes to your enrollment:
You can stop sharing your PHI with us or change what you share by calling us at 1-844-MED-MGNX, or by writing us at PO Box 3795, Chesterfield, MO 63006.

I have read and agree to the Patient HIPAA Authorization

Print Patient or Patient Representative Name ______________________

Signature of Patient or Patient Representative Name ______________________

Relationship to Patient ______________ Patient Social Security Number ______________

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Prescriber Information

Facility Name ______________________ Facility NPI # ______________________

Prescriber Name ______________________ Circle: D.O. M.D. N.P. P.A. R.Ph. Other ____________

Prescriber State License # ______________ HCP NPI # ______________________

Address ____

City ______________________ State ________ Zip ____________

Is the patient 18 years of age or older? ☐ Yes ☐ No

Office Phone ____________ Office Contact ______________________ Fax ____________

Prescription Order Information

SHIP MEDICATION TO PRESCRIBER ONLY. Medications cannot be shipped to Post Office (PO) boxes.

Infused Medication Treatment Setting:

☐ Hospital/Clinic Outpatient ☐ Prescriber's Office

Name of Treatment Facility ____

Address of Treatment Facility ____

☐ Product Replacement—Request product after dose administered ☐ Proactive Provision—Request product prior to administration

Date ______________________ ICD-10 ______________________

Patient Name ______________________ DOB ____________

Patient Address ______________________ Patient Phone ____________

City ______________________ State ________ Zip ____________

Is the patient 18 years of age or older? ☐ Yes ☐ No

Is the patient being treated for HER2+ metastatic breast cancer? ☐ Yes ☐ No

Is the patient going to be treated concomitantly with chemotherapy? ☐ Yes ☐ No

Has the patient received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease? ☐ Yes ☐ No

Drug Allergies ____

Other Medications ____

Patient Weight ____________

MARGENZA Directions ____

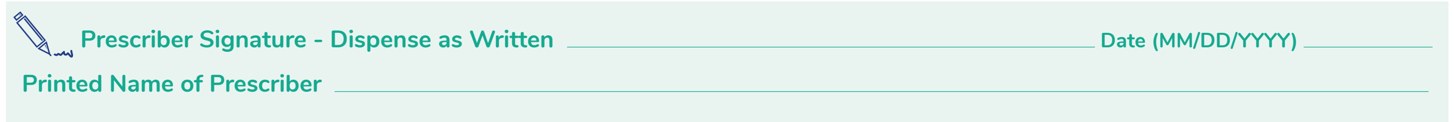
Scheduled Administration Dates ____

# of MARGENZA Single-dose Vials ______________________ Number of Refills ________

Recommended Dosing: 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.

Prescriber Signature (no stamps): I certify that I am the healthcare professional who has prescribed the above therapy to the previously identified patient, that I have made an independent judgment that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge. I authorize the MARGENZA Patient Support Program Representatives to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy, if applicable.

Your state may require that prescriptions follow certain content requirements, use a particular form, or in states with electronic prescription requirements, such as New York, prescriptions must be submitted via e-prescription directly to the pharmacy along with this enrollment form. By signing below, you certify that you are abiding by laws applicable to prescriptions and authorized prescribers in the state in which you are prescribing.



Prescriber Signature - Dispense as Written ______________________ **Date (MM/DD/YYYY)** ____________

Printed Name of Prescriber ____

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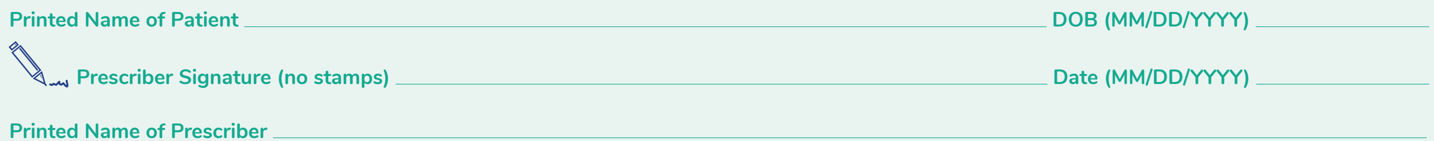
Prescriber Acknowledgment

By signing the below, I certify:

- The information provided is accurate to the best of my knowledge
- The therapy is medically necessary. I also represent that I am disclosing this information for treatment purposes as well as other medical information that may be disclosed, including medical records of the patient, to MARGENZA Patient Support, MacroGenics, Inc. ("MacroGenics"), and their vendors, business partners, and agents (the "Program Representatives") for the purpose of assessing whether the patient qualifies for the MARGENZA Patient Support program through the duration of the patient's therapy. I also certify that the patient is aware and has consented to my disclosure of their information to Program Representatives so that Program Representatives may contact the patient to further enable these services
- I am licensed and will comply with and abide by my State Practitioner dispensing laws for authorized prescribers in the state in which I am prescribing, receiving, storing, and dispensing the medication identified on this application to the patient listed in this application. I prescribed the medication to this patient based on my independent clinical judgment that treatment with this medicine for this patient is medically necessary
- I have prescribed this patient MARGENZA for an FDA-approved indication and/or compendia use
- To the best of my knowledge, the patient meets the financial, insurance, and residency requirements of the MARGENZA Patient Support program. If I become aware the patient may no longer meet the criteria for the program, I agree to notify MARGENZA Patient Support
- I have not received and will not seek reimbursement or payment for all or any part of the benefit received by the patient through MARGENZA Patient Support
- Any medication provided by MARGENZA Patient Support for this patient will not be resold, nor offered for sale, trade or barter, or returned for credit
- For insured patients, an appeal to the insurer has been completed, and I have received a denial for that appeal

I understand:

- MARGENZA Patient Support may change, terminate, or suspend participation, limit enrollment, or recall/discontinue medications in the program without prior notice
- I am under no obligation to purchase or prescribe any MacroGenics drug to participate in this program, and I have not received nor will I receive any benefit from any Program Representatives for prescribing a MacroGenics drug
- Program Representatives are not responsible for filing any insurance claim
- The information provided will be subject to potential random reviews
- If a retroactive insurer policy change allows for reimbursement of product already supplied at no charge, MARGENZA Patient Support will bill for the covered product, and I agree to be responsible for payment of the bill
- If I elect to receive medication from MARGENZA Patient Support under the Proactive Provision program, I certify that I will complete the required Administration Verification form confirming that the product has been administered to the applicable enrolled patient. I will notify MARGENZA Patient Support if any product is not administered to the applicable enrolled patient and will return the product to MARGENZA Patient Support for destruction or appropriately destroy the product at the facility and submit documentation to MARGENZA Patient Support confirming that the product has been appropriately destroyed. If I do not return or destroy the product provided and if it is not used for the applicable enrolled patient, I will be billed for the product, and I agree to be responsible for payment of the bill. (Please contact MARGENZA Patient Support at 1-844-MED-MGNX for assistance with product returns)



Printed Name of Patient ____________________ DOB (MM/DD/YYYY) __________

Prescriber Signature (no stamps) ____________________ Date (MM/DD/YYYY) __________

Printed Name of Prescriber ____________________

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Patient Support Program

What does MARGENZA treat?

MARGENZA is a prescription medicine approved for use 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

What is the most important information I should know about MARGENZA?

MARGENZA can cause serious side effects, including:

- **Heart problems that may affect your heart's ability to pump blood.** Your doctor will run tests to monitor your heart function before and during treatment with MARGENZA. Based on test results, your doctor may hold or discontinue treatment with MARGENZA.
  - Tell your healthcare provider right away if you get any of the following signs and symptoms: new or worsening shortness of breath, coughing, feeling tired, swelling of the ankles or legs, swelling of the face, irregular heart beat or palpitations, sudden weight gain of more than 5 pounds in 24 hours, dizziness or feeling light-headed, or loss of consciousness.
- **Harm to your unborn baby.** Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with MARGENZA. Exposure to MARGENZA during pregnancy or within 4 months prior to conception can result in fetal harm.
  - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with MARGENZA.
  - Birth control should be used while receiving MARGENZA and for 4 months after your last dose of MARGENZA.

What are other possible serious side effects of MARGENZA?

Infusion-related reactions. MARGENZA is a medicine that is delivered into a vein through a needle as an infusion. MARGENZA has been associated with infusion-related reactions which can include fever, chills, joint pain, cough, dizziness, tiredness, nausea, vomiting, headache, sweating, fast heart rate, low blood pressure, itching, rash, hives, and shortness of breath. Your healthcare team will monitor you during treatment with MARGENZA and may slow or stop your infusion if you have side effects. You may need to permanently stop MARGENZA if you have a severe infusion reaction.

Before you receive MARGENZA, tell your doctor if you are breastfeeding. It is not known if MARGENZA could pass into breast milk and harm your baby**.**

What are the most common side effects of MARGENZA in combination with chemotherapy?

The most common side effects with MARGENZA in combination with chemotherapy are fatigue/weakness, nausea, diarrhea, vomiting, constipation, headache, fever, hair loss, abdominal pain, peripheral neuropathy (weakness, numbness, pain, and/or tingling in hands and feet), joint and muscle pain, cough, decreased appetite, shortness of breath, infusion-related reactions, redness/swelling and pain on the palms of the hands and soles of the feet (hand-foot syndrome), and pain in arms and legs.

You are encouraged to 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).

These are not all the possible side effects of MARGENZA. Your doctor may stop treatment if serious side effects happen. Be sure to contact your healthcare team right away if you have questions or are worried about any side effects.

Please visit www.margenza.com for full Prescribing Information, including Boxed Warning.

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