Kyowa Kirin Cares Patient Assistance Program Application

Phone: 833-KK-CARES (833-552-2737) | **Fax:** 844-267-5848
Email: patientservices@kyowakirincares.com | **Hours:** M–F, 8AM to 8PM ET

Please complete application in full, sign and date, and fax to 844-267-5848

- PAP Application must be completed in order to be reviewed for patient program eligibility. Please ensure all areas of the form are completed in full, including all signatures.
- To be considered for the Patient Assistance Program, all applicants must satisfy the following requirements and eligibility criteria:
  - Applicants must complete the Financial Information section below, attach proof of income, and must qualify for the program financial requirements.
  - Applicants must be permanent United States resident (including all US Territories).
  - Applicants must be fully uninsured (no health insurance or prescription drug insurance whatsoever).
  - The requested product must be prescribed by a licensed U.S. healthcare professional for the Food and Drug Administration (FDA) approved indication.
- Each applicant will be individually assessed for program eligibility based on the information provided within this application.
- Applicants will only be evaluated for eligibility upon receipt of a completed and signed Kyowa Kirin Cares PAP Application.
- Patients with special circumstances such as financial and/or medical hardship that do not meet all of the PAP eligibility criteria, as determined in accordance with Kyowa Kirin Cares criteria, may submit an exception request for review. The decision to grant an exception is made at the sole discretion of Kyowa Kirin Inc, and is based on an individual's unique circumstances.

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Patient Information

Name: _____ DOB: _____ Last 4 SSN: _____ Gender: ☐ Male ☐ Female
First Middle Last (Required)

Address: _____ City: _____ State: _____ ZIP: _____

Cell Phone: _____ Home Phone: _____ Patient Email: _____

OK to Text? ☐ *By checking this box, I confirm this is my phone number and agree to subscribe to the Kyowa Kirin Cares Text Message program. I understand the amount of texts I receive may vary based on the progress of my enrollment.*

Preferred Contact Method: ☐ Cell Phone ☐ Home Phone ☐ Email Best Time to Call: ☐ Morning ☐ Afternoon ☐ Evening

Patient Information *(Documented Proof of Income is required if patient does not sign Electronic Income Verification Authorization)*

Total Annual Gross Household (HH) Income: $_____ Household Size (circle selection): (1) (2) (3) (4) (5) (6) _____

Select Your Sources of Income: ☐ Salary/Wages ☐ SS Pension/Unemployment ☐ Alimony/Child Support ☐ Retirement ☐ SSDI ☐ SSI

☐ No Household Income *($0 – Provide a signed letter from the patient explaining zero income)* ☐ Other: _____

Prescriber Information

Prescriber Name: _____ Prescriber NPI #: _____

Prescriber DEA: _____ Prescriber State License #: _____

Facility Name: _____ Facility HIN: _____

Facility Address: _____ City: _____ State: _____ ZIP: _____

Primary Office Contact: _____ Fax Number: _____

Phone Number: _____ Office Contact Email: _____

Product & Prescription Information

Rx: POTELIGEO (mogamulizumab-kpkc) – 20mg per 5mL Patient Weight: _____ kg

☐ Initiating Therapy – 1mg/kg IV QW for the first 5 infusions ☐ Maintenance – 1m/kg IV QOW

☐ Other Dosing (must indicate prescribed dosing & frequency): _____

Primary Diagnosis Code (ICD-10): _____ Primary Diagnosis Description: _____

Prescriber Certification

I certify that the information provided in this Patient Assistance Program Application is complete and accurate to the best of my knowledge, that I have prescribed POTELIGEO to the patient based on my professional judgment of medical necessity for a Food and Drug Administration (FDA) approved indication, and that I will supervise the patient's medical treatment. I will notify Kyowa Kirin Cares immediately if the Kyowa Kirin product is no longer medically necessary for this patient's treatment. I certify that I have obtained from my patient all required written authorizations for the release of my patient's personal identification and insurance information to Kyowa Kirin and their agents and representatives. I understand that any information provided is for the sole use of Kyowa Kirin and their agents and representatives to verify my patient's insurance coverage status, to assess, if applicable, patient's eligibility for participation in the Kyowa Kirin Cares Patient Assistance ("the Program"), and to otherwise administer the related services. I understand the application to the Program does not guarantee that assistance will be obtained. I understand that Kyowa Kirin may change or cancel this program at any time. I understand that if my patient's financial and/or insurance status changes, the patient may no longer be eligible for the Program, and I agree to immediately notify a Kyowa Kirin Cares representative if I become aware of changes in the patient's insurance status. I agree that Kyowa Kirin Cares may contact me for additional information relating to this application either by fax, e-mail, and/or telephone. I understand that I am under no obligation to prescribe any Kyowa Kirin product and that I have not received, nor will I receive any benefit from Kyowa Kirin or their agents or representatives for prescribing a Kyowa Kirin product. I agree that I will not submit claims or make any attempt to receive reimbursement for product provided by the Program. By signing this Patient Assistance Program Application, I authorize the release of medical and/or other patient information relating to POTELIGEO therapy to agents, and service providers of Kyowa Kirin (including but not limited to AllCare Plus Pharmacy, LLC and POTELIGEO-dispensing pharmacies) to use and disclose as necessary for verification of patient eligibility, and to furnish any information on this form to the insurer of the applicant for the purpose of verifying benefit eligibility.

Prescriber Certification Signature: _____ Date: _____
(original signature required)

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Patient Authorization and Agreement

By signing this Authorization, I authorize each of my prescribers, pharmacists, including any specialty pharmacy that receives my prescription for POTELIGEO (mogamulizumab-kpkc) and other healthcare providers (together "Healthcare Providers") and each of my health insurers (together, "Insurers") to disclose my Protected Health Information, including but not limited to medical records, information related to my medical condition and treatment, my health insurance coverage, my name, address, telephone number, Social Security number, insurance plan and or group numbers (together, "Protected Health Information") to Kyowa Kirin, its affiliated companies, vendors, agents, collaboration partners, and representatives (together, "Kyowa Kirin") including providers of alternate sources of funding for prescription drug costs, and other service providers supporting Kyowa Kirin Cares Patient Assistance (the "Program") for Healthcare Providers and patients for the purposes described below.

Specifically, I authorize disclosure of my Protected Health Information in order to:

I. Enroll me in, and contact me about the Program, including online support, financial assistance services, co-pay assistance, specialist services, and compliance and persistency services,

II. Communicate with my Healthcare Providers and Insurers about benefits, coverage and medical care, including compliance with Product treatments,

III. Locate a specialty pharmacy that can fill my prescription and facilitate dispensing of my prescription by such pharmacy,

IV. Provide me with educational materials, information and services related to my treatment experience with POTELIGEO and my condition,

V. Contact me and leave messages about my use of POTELIGEO and my medical care,

VI. Verify, investigate, assist with, and coordinate my coverage for POTELIGEO with my Insurers,

VII. Coordinate prescription fulfillment,

VIII. Conduct surveys, data analytics, market research and other internal business activities related to the Program, POTELIGEO, and other Kyowa Kirin products and programs, and

IX. Contact me as otherwise required or permitted by law.

Once my Protected Health Information has been disclosed to Kyowa Kirin, I understand that federal privacy laws no longer protect the information. However, Kyowa Kirin agrees to protect my Protected Health Information by using and disclosing it only for the purposes described in this authorization or as permitted by law. I understand that I may refuse to sign this Authorization. My choice about whether to sign will not change the way my Healthcare Providers or Insurers treat me, but I will not have access to the Kyowa Kirin Cares Program and the services provided by Kyowa Kirin under the Program. If I refuse to sign the Authorization, or revoke my authorization at a later time, I understand that this means I will not be able to participate or receive assistance from the Program.

I understand that I may cancel this Authorization at any time in the future, except to the extent that actions have been taken in reliance on the authorization, by mailing a request to 135 Route 202/206, Suite 6 Bedminster, NJ 07921, via fax at 844-267-5848, or by calling 833-552-2737. I understand that revoking this Authorization will end further uses and disclosure of my Protected Health Information by the parties identified above except to the extent those uses and disclosures have been made in reliance upon this Authorization as permitted by applicable law. I am entitled to receive a copy of this Authorization.

I understand that if I qualify and I am enrolled in the Program sponsored by Kyowa Kirin, I will receive POTELIGEO from Kyowa Kirin only pursuant to a legally valid prescription from my health care provider. I understand that if I qualify and I am enrolled in the Program, Kyowa Kirin will provide me POTELIGEO free of charge for the duration of the enrollment period so long as I have a legally valid prescription for POTELIGEO. I understand that I am not required to continue treatment with POTELIGEO if I gain insurance coverage, or to receive treatment from any given provider. I understand and agree that I must notify Kyowa Kirin Cares at 833-KK-CARES immediately if my insurance status changes during the Program enrollment period. I understand and agree that neither I nor my Insurers, if applicable, will be charged for the supply of POTELIGEO that I received from the Program, and that under NO circumstances may I claim reimbursement from my Insurers or any related third party for the POTELIGEO provided to me free of charge from the Program. I understand that Kyowa Kirin reserves the right at any time without notice to modify or discontinue the Program and its criteria.

I understand that I am providing 'written instructions' to Kyowa Kirin and its vendor Sonexus Health, LLC under the Fair Credit Reporting Act authorizing AllCare Plus Pharmacy, LLC on behalf of Kyowa Kirin to obtain information from my credit profile or other information from Experian Health. I authorize Kyowa Kirin and its partnered provider AllCare Plus Pharmacy, LLC to obtain such information solely for the purpose of determining financial qualifications for the Program. I understand that I must affirmatively agree to the terms in this notice by signing below in order to proceed in the Program financial screening process.

My signature certifies that I have read and understand the above statements, and agree to the outlined terms.

Patient Name (Print): _____ Patient Signature: _____ Date: _____

Patient Authorization and Agreement

I permit Kyowa Kirin Cares Support Services representatives to speak with the following person about this enrollment form. This includes discussing the status of my application, insurance and financial questions, any missing documentation and other issues related to my enrollment, insurance appeals, or any other treatment related issues. I may cancel this authorization at any time by calling: 833-552-2737.

Name of Authorized Representative: _____ Relationship to Patient: _____

Telephone Number: _____ Email: _____

By signing below, I, the patient, allow this representative to speak on my behalf on any matter regarding my enrollment with the Program.

Patient Signature: _____ Date: _____

INDICATION

POTELIGEO® (mogamulizumab-kpkc) injection for intravenous infusion is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Dermatologic toxicity:** Monitor patients for rash throughout the course of treatment. For patients who experienced dermatologic toxicity in Trial 1, the median time to onset was 15 weeks, with 25% of cases occurring after 31 weeks. Interrupt POTELIGEO for moderate or severe rash (Grades 2 or 3). Permanently discontinue POTELIGEO for life-threatening (Grade 4) rash or for any Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).

- **Infusion reactions:** Most infusion reactions occur during or shortly after the first infusion. Infusion reactions can also occur with subsequent infusions. Monitor patients closely for signs and symptoms of infusion reactions and interrupt the infusion for any grade reaction and treat promptly. Permanently discontinue POTELIGEO for any life-threatening (Grade 4) infusion reaction.

- **Infections:** Monitor patients for signs and symptoms of infection and treat promptly.

- **Autoimmune complications:** Interrupt or permanently discontinue POTELIGEO as appropriate for suspected immune-mediated adverse reactions. Consider the benefit/risk of POTELIGEO in patients with a history of autoimmune disease.

- **Complications of allogeneic HSCT after POTELIGEO:** Increased risks of transplant complications have been reported in patients who received allogeneic HSCT after POTELIGEO. Follow patients closely for early evidence of transplant-related complications.

Adverse Reactions

- The most common adverse reactions (reported in ≥10% of patients) with POTELIGEO in the clinical trial were rash, including drug eruption (35%), infusion reaction (33%), fatigue (31%), diarrhea (28%), drug eruption (24%), upper respiratory tract infection (22%), musculoskeletal pain (22%), skin infection (19%), pyrexia (17%), edema (16%), nausea (16%), headache (14%), thrombocytopenia (14%), constipation (13%), anemia (12%), mucositis (12%), cough (11%), and hypertension (10%).

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-844-768-3544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.