

## POTELIGEO® PRODUCT RETURN POLICY FOR CUSTOMERS

Effective Date: **June 1, 2018**

This Product Return Policy (“the Policy”) is for Poteligeo (mogamulizumab-kpkc) Injection (“Product” or “Products”) distributed in the United States by Kyowa Kirin, Inc. (“KKI”) that were purchased from an authorized distributor of record (“ADR”), as listed on the KKI website. KKI retains the right to discontinue this Product Return Policy for any customer, whom KKI determines, in its sole discretion, has misused this Product Return Policy and/or misrepresented the reason for returning Product.

Customer or customers are defined as entities that purchase and take ownership title of the Products and have the capabilities to mix and administer the Product on a patient. KKI clarifies there are separate return policies governing purchases by an ADR directly from KKI or KKI’s other products such as Sancuso.

**KKI will issue credit or free replacement products (in certain situations, replacement product only) for products that are eligible for return in accordance with the terms of this Policy, and the associated written return request has been approved by KKI.**

### **1. Products Not Eligible for Return Credit (or Replacement)**

- A. Product that has been mixed, and administered to a patient.
- B. Product that KKI has previously designated as “non-returnable” by contract or notice to Customer outside of the Policy.
- C. Product that is otherwise adulterated, misbranded, or counterfeit, as deemed by KKI in its sole discretion.
- D. Product that has been repackaged.
- E. Product purchased for research or clinical trials.
- F. Product shipped as a no cost item (e.g., physician sample, patient assistance program product etc.).
- G. Customer has received, or is in the process of receiving, credit or reimbursement from any party other than KKI for the Product involved.
- H. Products returned by a third party processor (such as a reverse logistics vendor) acting on behalf of the Customer without an approval by KKI on the request filed by the Customer in advance.

**2. Customer Returns: Product is eligible for return and replacement or credit (or, in certain circumstances, replacement only) from Customers where the Product satisfies the requirements in any one of sub-sections (A) through (G) below.**

#### A. Damaged Product

Product shipped directly from KKI that is damaged in transit from KKI. Such damaged Product shall be immediately reported to KKI Trade Operations (1-833-590-7709). For Products that are purchased by Customer from an ADR, the Customer shall contact the ADR directly.

#### B. Product Quality Concerns

Product that is unusable due to a quality issue related due to the manufacturing of the Product (i.e., the visible physical characteristics of the Product deviate from the physical characteristics of the Product described in the prescribing information for the Product); and the product quality complaint has been reported to KKI. Please report product quality complaints to KKI Medical Information at 844-768-3544.

#### C. Product within Expiration Window

Product that is returned within three (3) months before or after the expiration date of the Product (“Expiration Window”). Products expire on the last day of the month indicated on the packaging.

Product returned any time before or after the Expiration Window, and that does not otherwise qualify for a return as set forth herein, will be deemed as “Not Returnable” unless allowed by other applicable state laws. Not Returnable Product will be destroyed by KKI or its agent or designee (i.e., Cardinal 3PL) and credit will not be given to the returning Customer.

#### D. Product Ordered by a Customer for a Specific Patient That Could Not Be Used

Product ordered but not yet administered to a specific patient because:

1. Such patient has discontinued use of the Product due to an adverse event, patient death, or any other reason that prevents the patient from continuing therapy with the Customer seeking to return the Product, and
2. Such Customer has certified that Product cannot otherwise be used for such patient or any other patient before three (3) months prior to expiration date.

#### E. Product Returned At Direction of KKI

Product that KKI, in its sole discretion, has specified to be returned.

#### F. Certain Product Loss Due to a Major Disaster with no Insurance Coverage

Product purchased by Customers, excluding wholesalers, distributors, retail pharmacies, mail-order pharmacies, and specialty pharmacies that is in a deteriorated condition if the following conditions have been met:

- 1) The Customer has certified that the Product deterioration is the direct result of a natural disaster that has been declared as a “Major Disaster” by the President of the United States under Section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, PL 100-707 (42 U.S.C. 5170) with respect to the geographic location of the applicable Product;
- 2) The Customer has certified that no insurance, indemnity or similar type of policy or program (regardless of deductible, copayment or any similar concept) covers the damage or loss resulting from such Major Disaster;
- 3) Such Product is either returned to KKI or the Customer has certified that such Product was destroyed as a result of the Major Disaster and cannot be physically returned;
- 4) Product shall be eligible for replacement only (no credit will be issued).
- 5) Replacement of Product(s) is limited to an aggregate for all Products of \$50,000, based on the prevailing wholesale acquisition cost (“WAC”), per Customer per Major Disaster;
- 6) Any claims for replacement Product must be received by KKI within two (2) subsequent calendar quarters following the declaration date of the Major Disaster as specified on the Federal Emergency Management Agency’s website;

- 7) KKI reserves the right to reject any request for replacement of Product to the extent that KKI in its sole discretion determines that such request involves fraudulent documentation or tampered Product.

#### G. Product Spoilage

Product that is spoiled and unable to be administered if spoilage was due to one of the following events:

- 1) Product was mishandled, dropped, or broken;
- 2) Product was inappropriately stored or refrigerated, or was frozen;
- 3) Admixture error;
- 4) Product was reconstituted but not administered due to an unforeseen patient condition or because the patient missed the appointment.

Additional conditions for replacement of spoiled Product:

- Product shall be eligible for replacement only (no credit will be issued).
- Samples are not eligible for spoilage replacement.
- Replacement is not available if Product has been administered.
- KKI can ship replacement Product only to licensed entities.
- All spoilage replacement requests are subject to review.
- If already billed to the patient or insurance, then replacement is not available. Customers must sign an acknowledgement that neither the patient nor a payor was billed for the spoiled Product.
- If a co-pay or co-insurance payment was received, then replacement is not available.
- Replacement due to loss of refrigeration is limited to five (5) packs per incident, based on SKU dispensing pack quantity. In all other instances of spoilage, replacement is only allowed for single Product claims; it does not cover multi-unit losses.
- Customer is required to submit documentation detailing how spoilage occurred.
- If the Spoiled Product is not returnable (e.g. broken vial), the Customer must attest to how it became unusable and include a photograph of the spoiled Product.
- Customers must sign an acknowledgement that neither the patient nor a payor was billed for the spoiled Product

### **3. Additional Requirements for Product Returns: Product qualifying for return under section (2) must also satisfy the requirements in this section (3).**

- A. Product must have been purchased directly from KKI or from an ADR with proof of purchase.
- B. Product must be returned in original packaging with label intact and fully readable including NDC, lot number, expiration date, unless
  - (1) A certification of return circumstances that would not require the return of physical Product (e.g. loss, damage, etc.) and proper disposal has been submitted and KKI has approved and processed such certification or
  - (2) Product is physically returned but is damaged making fulfillment of this requirement impossible.
- C. All eligible Products returned in accordance with and subject to the terms and conditions set forth herein are subject to valuation by KKI in its sole discretion. Unless otherwise specified in a notice from KKI (e.g., recall notice), Products returned shall be credited at the original purchase

price.

- D. If KKI is unable to accurately determine the original purchase price of the Products, the Products returned for credit for reasons other than Products that are returned within the Expiration Window shall be credited based on the lower of any of the Customer's contracted or government mandated prices at the time of return or the prevailing WAC at the time of return.

Products that are returned within Expiration Window shall be credited based on the lower of any of (1) the Customer's contracted or government mandated prices at the time of return less ten percent (10%), or (2) the prevailing WAC at the time of return less ten percent (10%), or (3) the contracted price at time of purchase less ten percent (10%).

#### 4. Return Shipments

- A. KKI requires the following detail from all Customers that purchased the Product and are returning the Product pursuant to the The Policy:

- Copy of the invoice documenting the purchase.
- Returning Customer Facility Details: Name, Address, City, State, Zip Code, DEA Number (If Applicable)Product Details: Product Description, Quantity, NDC Number, Lot Number, Expiration Date

- B. All Products returned during the Expiration Window must be sent to Cardinal 3PL for processing and destruction. For Product returns during the Expiration Window the customer must contact Cardinal 3PL for instructions at 614.652.0271 or [GMB-SPS>Returnsrequests@cordlogistics.com](mailto:GMB-SPS>Returnsrequests@cordlogistics.com) or TradeRelations-US@kyowakirin.com

- C. Credit for eligible returns will be issued per KKI terms noted herein unless state and local law requires otherwise.

- D. Products that are returned and do not meet the criteria set forth in this Policy for return and credit may be sent to Cardinal 3PL for disposal and destruction. Products that are returned and do not meet the criteria set forth in this Policy will be destroyed and will not be eligible for replacement product or credit.

- E. All other Product returns contact KKI Trade Relations for instructions at 908.375.2360 or toll free 833.590.7709 or TradeRelations-US@kyowakirin.com

- F. The piece count to determine credit will be performed by either KKI or Cardinal 3PL and will be considered as final. The shipping address for returned merchandise is:

Cardinal 3PL  
Kyowa Kirin Returns Department  
15 Ingram Blvd, Dock 43  
LaVergne, TN 37086

- G. In cases where Product is being returned solely because it falls within the Expiration Window, Customers are responsible for the cost of shipping Product to KKI or KKI's returns processing agent, Cardinal 3PL, and are liable for the Product until Cardinal 3PL or KKI receives the

returned Product.

- H. For Products that are returned within the Expiration Window, KKI will neither pay for nor reimburse any Customer for any return goods transportation costs, handling fees, or processing fees incurred on the part of the Customer or Customer's return goods processor.
- I. For all other eligible returned Product, cost of shipping shall be paid by KKI.
- J. KKI is not responsible for return shipments lost in transit or received in damaged condition.

## **5. Batch Returns**

KKI will not issue credit for consolidated or batch returned Product from multiple facilities or Customers via one memo. The physical return must be segregated by returning entity and debit memo.

## **6. General Information**

All responses to return inquiries will only be provided to the returning Customer on record.

KKI may, in its sole discretion, make exceptions, changes and/or modifications to the Policy at any time and without prior notice to other parties. Return product shipments that are deemed to be outside of the Policy will not be returned to the Customer or the third party processor and no credit will be issued by KKI for the Products unless state or local law requires otherwise.

All ADRs and Customers are required to adhere to the regulations and business practices required by the Drug Supply Chain Security Act (DSCSA) and any other federal, state or local laws, rules or regulations that are defined for reverse logistics.

Questions regarding this The Policy can be directed to KKI Trade Operations at 908.375.2360 or toll free 833.590.7709 or email [TradeRelations-US@kyowakirin.com](mailto:TradeRelations-US@kyowakirin.com)