



PRODUCT RETURN POLICY

Effective Date: **October, 27, 2015**

This Product Return Policy ("Product Return Policy") is for all Products ("Product" or "Products") distributed in the United States by Amgen USA Inc. ("Amgen").¹ Note that this Product Return Policy contains distinct terms and conditions for returns from entities that purchase product from Amgen directly or from an authorized distributor of record, as defined below, ("Customer or Customers") versus returns from Patients.²

1. Customer Returns: Product is eligible for return and 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) Certification of circumstances of return satisfying the requirements of one of sub-sections (A), or (C) through (G) below is required to process the return and credit or replacement, as applicable.
- b) Unused Product must be returned to Amgen as outlined in Section 3 below unless (a) a certification of return circumstances that would not require the return of physical Product (e.g. loss, damage, etc.) and proper disposal, if applicable, has been submitted and Amgen has approved and processed such certification or (b) Product is physically returned but is damaged making fulfillment of this requirement impossible. Notwithstanding the foregoing, Sub-section B requires the physical return of Product in all instances.

A. Damaged Product

Product shipped directly from Amgen that is damaged in transit from Amgen shall be processed exclusively by Amgen. Such damaged Product shall be immediately reported to Amgen Trade Operations (1-800-282-6436).

- 1) *Quality Concerns:* Product purchased directly from Amgen by direct purchasing accounts, or from an authorized distributor of record set forth on the Amgen external website ("ADR,") that is unusable due to reasons related to Product quality arising out of the manufacturing of the Product (i.e., the physical characteristics of the Product deviate from the physical characteristics of the Product described in the prescribing information for the Product) shall be processed exclusively by Amgen. Please contact Amgen Medical Information at 800-77-AMGEN (800-772-6436). This section shall also apply to situations in which the Customer discovers that the freeze indicator has been triggered through no fault of the Customer and specifically for IMLYGIC™ (talimogene laherparepvec) returns, instances where the shatterproof vial breaks.

¹ This Product Return Policy relates to Product distributed and received in the United States and the United States Territories only and is subject to certain limitations and conditions as set forth in this Product Return Policy.

² Amgen retains the right to discontinue this Product Return Policy for any Customer or Patient, whom Amgen determines, in its sole discretion, has misused this Product Return Policy and/or misrepresented the reason for returning Product.

- 2) *Neulasta[®] Delivery Kit On-body Injector* for *Neulasta Failure*: Product purchased directly from Amgen or from an authorized distributor that is unusable due to malfunction or failure of an Amgen-furnished On-body Injector for Neulasta (“OBIN”) for the Product, including situations where such a OBIN did not perform as described in the Healthcare Provider and/or Patient Instructions for Use. Returns under this provision shall not include instances where the OBIN and associated Product were improperly stored or were improperly handled by the customer such that the OBIN and/or Product were rendered unusable prior to any attempt to activate and apply the OBIN (e.g., OBIN or prefilled syringe dropped and broken, Product not refrigerated according to Product Instructions for Use, etc.).

B. Product Within Expiration Window

Product purchased either directly from Amgen, or from an ADR, to the extent that the Product is returned no earlier than three (3) months prior to the expiration date of the Product and no later than twelve (12) months after the expiration of the Product (“Expiration Window”).³ Products expire on the last day of the month indicated on the packaging.

C. Product Ordered For Specific Patient That Could Not Be Used

Product purchased directly from Amgen by direct purchasing accounts or from an ADR for administration to a specific patient and:

- 1) Such patient has discontinued use of the Product due to one of the following reasons: adverse event, patient deceased, or any other reason that permanently 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 any other patient prior to three months prior to expiration date.

D. Product Ordered In Error

Product ordered and purchased from Amgen by a direct Customer and returned due to Customer’s ordering error. Such Product shall only be returnable if a Customer notifies Amgen of the error in writing within 3 business days of receipt of the shipment pertaining to the ordering error and Amgen confirms receipt of request to return.

E. Product Returned By Patient to Customer and Replaced By Customer

Product dispensed to and returned by a Patient to a Customer and subsequently replaced by Customer, provided:

- 1) The product would qualify for replacement if returned directly by the Patient in accordance with Section (2) below, and
- 2) The Customer has certified that it has not and will not obtain payment for the replacement Product through the applicable Patient’s third-party payor or the Patient him/herself.

³ Product returned any time before or after the Expiration Window, and that does not otherwise qualify for a return as set forth herein, shall be registered as “Not Returnable” and will be immediately destroyed by Amgen or its agent or designee (i.e., Genco) and credit will not be given to the returning Customer. Amgen recommends that before a return is made, please confirm with Amgen or its agent or designee (i.e., Genco) that the Product is within the Expiration Window related to the expiry date on the Product, as no exceptions can be made.

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

Product (other than Enbrel[®], EPOGEN[®] and Sensipar[®]) purchased by Customers (other than distributors (including ADRs) and pharmacies (including retail pharmacies, specialty pharmacies and mail-order pharmacies but not including hospital-based pharmacies)) that is in a deteriorated condition due to improper storage or loss of refrigeration (e.g., exposure to water, heat, cold, fire) if the following conditions have been met:

- 1) The Customer has certified that the improper storage or loss of refrigeration is the direct result of a natural disaster that has been declared 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” of the Product or any of Customer’s other pharmaceutical products;
- 3) Such Product is either returned to Amgen 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) and replacement of Product shall be limited to amounts in full packaging amounts only and no replacement Product or credit will be available to the extent that such Product is in excess of a full packaging amount;
- 5) Replacement of Product(s) is limited to an aggregate for all Products of \$100,000 (based on the then prevailing WAC of the applicable Product(s)) per Customer per “Major Disaster” and no replacement of Product or credit will be available for any loss in excess of such amount;
- 6) Any claims for replacement Product must be received by Amgen within two subsequent calendar quarters following the declaration date of the “Major Disaster” as specified on the Federal Emergency Management Agency’s website;
- 7) Any certification by a Customer required by this section 1(F) shall be in writing in a form acceptable to Amgen (including any supporting documentation requested by Amgen) and shall be attested to by the lead physician of a practice/clinic or the chief executive, financial or operating officer of a hospital or similar institution, as the case may be; and
- 8) Amgen reserves the right to reject any request for replacement of Product to the extent that Amgen in its sole discretion determines that such request involves fraudulent documentation or tampered Product.

G. Product Returned At Direction of Amgen

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

H. Returns of IMLYGIC[™] Product

- 1) Amgen will provide credit or replacement for returns of IMLYGIC[™] (“IMLYGIC[™] Product”) that : (i) have been compromised and rendered not usable, (ii) have not been



administered to a patient, and (iii) have not been billed to or reimbursed by a third party payor in the following circumstances:

- (a) Patient is unavailable for IMLYGIC™ Product administration (*i.e.*, IMLYGIC™ Product was prepared for a particular patient and that patient is unavailable, for any reason, to have the IMLYGIC™ Product administered); or
- (b) Loss of temperature stability (*i.e.*, IMLYGIC™ Product that is not maintained at the required temperature per the IMLYGIC™ Product Insert). Loss of temperature stability shall be a returnable circumstance except for instances of loss of refrigeration due specifically to failure of refrigeration equipment (for any reason) owned and maintained by the returning entity. However, IMLYGIC™ Product returns associated with the loss of temperature stability due to the failure of refrigeration equipment provided by Amgen, where such failure of equipment was at no fault of the returning party, shall be returnable under this section.

2) Amgen reserves the right to monitor and audit Customer's compliance with this Product Return Policy and to refuse any return request that otherwise meets the above criteria.

2. Patient Returns: Product is eligible for return and replacement from Patients where the Product satisfies the requirements of this section (2) below.⁴

Product sold to a Patient where the Patient has lost or damaged product or articulated concern(s) regarding his/her use of the product to be returned and replaced. The Patient's concern(s) regarding use of the original product or situation necessitating return must be documented.

3. Additional Information and Requirements for Product Returns: Product qualifying for return and credit (or in certain circumstances, replacement only) under section (1) must also satisfy the requirements in this section (3).

- A. Product must have been purchased directly from Amgen or from an ADR with proof of purchase (supplied by the returning party upon request by Amgen or its agent or designee).
- B. Product must be returned in original packaging with label intact and fully readable including NDC, lot number, expiration date, unless (a) 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 Amgen has approved and processed such certification or (b) Product is physically returned but is damaged making fulfillment of this requirement impossible.
- C. Product in partial quantities will be accepted only if returned in its original packaging (*i.e.* the Amgen original vial, syringe or individual bottle,) unless (a) a certification of return circumstances that would not require the return of physical Product (e.g. loss, damage, etc.) and proper disposal, if applicable, has been submitted and Amgen has approved and processed such certification or (b) Product is physically returned but is damaged making fulfillment of this requirement impossible. This section (C) does not require that partial quantities be returned in the outer packaging which aggregated the individual vial, syringe or bottle at the outset of shipment. All Products returned, including Products Not Eligible for Return For Credit (as defined below), will be destroyed.

⁴ Note that any allowable return by a Patient under this Product Return Policy is eligible for Product replacement only. The Patient will not be reimbursed any copayment or other amount.

- D. All eligible Products returned in accordance with and subject to the terms and conditions set forth herein are subject to valuation by Amgen in its sole discretion. Unless otherwise specified in a notice from Amgen (e.g., recall notice), Products returned for reasons other than (i) within the Expiration Window or (ii) as a result of a Major Disaster pursuant to section 1(F) shall be credited based on the lower of any of the Customer's contracted or government mandated prices at the time of return or, if not applicable, then credit shall be based on the prevailing wholesale acquisition cost ("WAC") at the time of return. Products 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 less ten percent (10%), or if not applicable, then credit shall be based on the prevailing WAC at the time of return less ten percent (10%). For the purposes of this Product Return Policy, contracted price shall be calculated using WAC in effect at the time of the return less the contracted invoice discount, but such calculation shall exclude any contracted rebate.

4. Products Not Eligible for Return For Credit: For the avoidance of doubt, the following Product is not eligible for return for credit under section (1) above, regardless of whether the Product otherwise satisfies the requirements in any one of sections (1) sub-sections (A) through (G) above:

- A. Product in which the NDC, lot numbers and/or expiration dates are missing, covered and/or illegible on original container, unless deemed nonreturnable by Amgen and a certification of damage has been approved and processed, unless (a) a certification of return circumstances that would not require the return of physical Product (e.g. loss, damage, etc.) and proper disposal, if applicable, has been submitted and Amgen has approved and processed such certification or (b) Product is physically returned but is damaged making fulfillment of this requirement impossible.
- B. Product that is not in its original container and/or not bearing its original label, unless (a) a certification of return circumstances that would not require the return of physical Product (e.g. loss, damage, etc.) and proper disposal, if applicable, has been submitted and Amgen has approved and processed such certification or (b) Product is physically returned but is damaged making fulfillment of this requirement impossible.
- C. Product that was purchased from sources outside of the United States.
- D. Product involved in a fire, flood, natural disaster, or obtained in a sacrifice or bankruptcy sale except for Product returned by (i) a Patient and satisfying the requirements of section (1)(E) or (ii) a Customer satisfying the requirement of section 1(F), which shall be an allowable return.
- E. Product that is in a deteriorated condition due to improper storage or loss of refrigeration (e.g., exposure to water, heat, cold, fire) except for product returned by (i) a Patient and satisfying the requirements of section (1)(E) or (ii) a Customer satisfying the requirements of section 1(F), which shall be an allowable return.
- F. Product that Amgen has previously designated as "nonreturnable" by contract or notice to Customer outside of the Product Return Policy.
- G. Product that is otherwise adulterated, misbranded, or counterfeit, as determined by Amgen in its sole discretion.
- H. Product that has been repackaged.
- I. Product purchased for research or clinical trials or shipped as a no cost item (e.g., physician sample, Product replaced through separate Amgen Product replacement program, etc.).
- J. Product that is returned prior to three (3) months before or after twelve (12) months after the expiration of Product that otherwise does not satisfy sections (1) sub-section (A) or sub-sections (C)-(G) above,
- K. Product damaged or rendered unusable due to mishandling or error by Customer.



5. Return Shipments

- A. Amgen requires the following detail from all ADRs or Customers that purchased Amgen Product and are returning the Product pursuant to the Product Return Policy:

Authorized Distributor/Wholesaler Details: Name, Address, City, State, Zip Code, DEA Number (If Applicable)

Returning Customer Facility Details: Name, Address, City, State, Zip Code, DEA Number (If Applicable)

Debit Memo Details: Debit Memo Number, Debit Memo Date, Debit Memo Amount

Product Details: Product Description, Quantity – Full or Partial, NDC Number, Lot Number, Expiration Date.

- B. All Products returned during the Expiration Window must be sent to Genco (formerly Capital Returns, Inc.) for processing and destruction.
- C. Credit for eligible returns will be issued per Amgen terms noted herein unless state and local law requires otherwise.
- D. Products that do not meet the criteria set forth in this Product Return Policy for return and credit may be sent to Genco for disposal and destruction.
- E. The piece count to determine credit will be performed by either Amgen or Genco and will be considered final. The shipping address for returned merchandise is:

Genco Pharmaceutical Services
Amgen Return Goods
6101 North 64th Street
Milwaukee WI 53218
1-414-967-2800

- F. For Customers returning through other third party processors, Amgen will not issue credit if the third party processor does not provide the required information noted above to Genco.
- G. Returns from third party processors acting on behalf of Customers will be accepted provided that the third party processor complies with all aspects of this Product Return Policy. Amgen is not responsible for fees incurred by third party processor.
- H. 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 Amgen or Amgen's returns processing agent, Genco, and are liable for the Product until Genco or Amgen receives the returned Product.
- I. Cost of shipping returned Product that is eligible for credit (or replacement) under this Product Return Policy, except for Product returned pursuant to the Expiration Window, shall be paid by Amgen.
- J. Amgen is not responsible for return shipments lost in transit or received in damaged condition.
- K. Amgen will neither pay for, nor reimburse, an ADR or any other Customer for any return goods transportation costs, handling fees, or processing fees incurred on the part of the ADR or ADR's return goods processor. ADRs are specifically prohibited from deducting from any payment any such return transportation costs, handling fees or processing fees.



- L. Full and partial returns of Product involving an Amgen chargeback shall follow the process set forth in the Amgen Chargeback Policy.

6. Batch Returns

- A. Amgen will not issue credit for consolidated or batch returned Product from multiple facilities or Customers on one debit memo. The physical return must be segregated by returning entity and debit memo. For returns from ADRs, credit will be issued in the form of a credit memo.
- B. For returns from non-ADR accounts, credit will be issued directly to returning Customer in the form of a check or credit memo issued to Customers from Amgen.

7. General Information

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

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

Questions regarding this Product Return Policy can be directed to Amgen Trade Operations 1-800-282-6436.