



PRODUCT RETURN POLICY

Effective Date: **October 1, 2022**

This Product Return Policy (“Product Return Policy”) is for all Amgen products (“Product” or “Products”) distributed in the United States by Amgen USA Inc. (“Amgen”) that were purchased from Amgen directly or from an authorized distributor of record (“ADR”), as listed on the Amgen website (“Customer” or “Customers”).^{1, 2}

1. 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 (I) below.

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, TradeOPSFax@amgen.com).

B. Product Quality Concerns

Product 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).

C. Product Within Expiration Window

Product that is received at Amgen’s third-party processor, PharmaLink, 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.

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

Product not 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

¹ 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 For patient replacements, please refer to Section 3 below.

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 third-party processor and credit will not be given to the returning Customer. Amgen recommends that before a return is made, Customer confirm with Amgen or its third-party processor that the Product is within the Expiration Window related to the expiry date of the Product, as no exceptions can be made.

- 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 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 Customer notifies Amgen of the error in writing within five (5) business days of receipt of the shipment pertaining to the ordering error and Amgen confirms receipt of request to return.

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

Product was dispensed to and returned by a patient to a Customer and subsequently replaced by Customer; provided, however, both that the return complies with the requirements set forth in Section 3 and the Customer has certified that it has not and will not obtain payment for the replacement Product through the patient's third-party payor or the patient.

G. Product Returned At Direction of Amgen

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

H. 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 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 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);
- 5) Replacement of Product(s) is limited to an aggregate for all Products of \$100,000, based on the prevailing wholesale acquisition cost ("WAC"), per Customer per Major Disaster;
- 6) Any claims for replacement Product must be received by Amgen 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) 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.

I. 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) There was an 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).
- Spoilage applies only to infused or injected Products.
- Replacement Product only available where quantity of spoiled Product is available in a FDA approved packaging configuration. Requests for replacement of partial packs cannot be fulfilled.
- Samples are not eligible for spoilage replacement.
- Replacement is not available if Product has been administered.
- Amgen can ship replacement Product only to licensed entities.
- All spoilage replacement requests are subject to review.
- If already billed or submitted to insurance, or a co-pay or co-insurance payment was received, replacement is not available.
- Replacement due to loss of refrigeration is limited to five (5) packs per incident, based on SKU dispensing pack quantity, unless the loss was caused by the failure of an Amgen-provided refrigerator.

2. Additional Requirements for Product Returns: Product qualifying for return under section (1) must also satisfy the requirements in this section (2).

- A. Product must have been purchased directly from Amgen or from an ADR with proof of purchase.
- B. Product must be returned to Amgen or its third-party processor in original packaging with label intact and fully readable including NDC, lot number, expiration date, serial number, 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 or (c) Amgen provides prior authorization for Customer to safely and compliantly destroy Product. 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 as set forth in Section 4, will be destroyed.
- D. Customer shall segregate and identify any returned Product that was purchased under the



Public Health Service 340B Drug Pricing Program (“340B Program”) 340B Program.

- E. 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 shall be issued reimbursements based on the following:

Product returned solely for falling within the Expiration Window:

- 1) ADRs shall be credited at 90% of prevailing WAC at time of return.
- 2) All other eligible Customers, shall be credited at 90% of the lower of (1) the Customer’s price at the time of return, or (2) the Customer’s price at the time of purchase.

Product returned for reasons other than falling within the Expiration Window:

- 3) ADRs and eligible Customers shall be credited based on the lower of (1) the Customer’s or ADR’s price at the time of return, or (2) the Customer’s or ADR’s price at the time of purchase.

3. Patient Replacements: Patients are eligible for replacement Product only (credit is not available) where the Product satisfies the requirements below.

- A. Product sold to a patient by a Customer where the patient has articulated concern(s) regarding his/her use of the Product to be replaced or lost or damaged Product. Common examples include, but are not limited to:

- 1) Product complaints due to administration or Product quality concerns;
- 2) Product which has exceeded the required temperature storage conditions for use; and
- 3) Loss due to events such as a natural disaster, fire, flood, or theft.

Any patient concern regarding use of the original Product or situation necessitating replacement must be documented and is subject to review by Amgen, in its sole discretion.

- B. Additional considerations for patient replacements:

- 1) The patient will not be reimbursed any copayment or other amount.
- 2) Product shipped as a no-cost item (e.g., sample) will not be eligible for replacement.
- 3) Replacement Product is only available where the quantity of Product to be replaced is available in a FDA-approved packaging configuration. Requests for replacement of partial packs cannot be fulfilled.
- 4) Replacement due to loss of the Product is limited to a maximum 3-month supply per request.
- 5) Amgen may request Product be returned prior to providing replacement Product.
- 6) Amgen is not responsible for damage or loss incurred during the course of shipment of Product from the patient’s pharmacy to the patient. Such replacement requests should first be managed by the patient directly with his/her pharmacy.
- 7) Amgen cannot ship replacement Product to a patient’s pharmacy.

- C. Requests for a replacement:



- 1) Contact Amgen Medical Information at 800-77-AMGEN (800-772-6436) to determine replacement eligibility.
- 2) Amgen may verify the patient's prescription with the patient's healthcare provider before providing replacement Product.
- 3) Amgen may contact the patient to schedule delivery of Product.

4. Products Not Eligible for Return: The following Product is not eligible for return:

- A. Product that Amgen has previously designated as "nonreturnable" by contract or notice to Customer outside of the Product Return Policy.
- B. Product that is otherwise adulterated, misbranded, or counterfeit, as determined by Amgen in its sole discretion.
- C. Product that has been repackaged.
- D. Product purchased for research or clinical trials.
- E. Product shipped as a no-cost item (e.g., physician sample, Product replaced through separate Amgen Product replacement program, etc.).

5. Return Shipments

- A. Amgen requires the following information be supplied with shipment from all ADRs or Customers that purchased Amgen Product and are returning the Product pursuant to the Product Return Policy:

Return Information:

- 1) Authorized Distributor/Wholesaler Details: Name, Address, City, State, Zip Code, DEA Number (If Applicable)
 - 2) Returning Customer Facility Details: Name, Address, City, State, Zip Code, DEA, HIN and 340B ID Number (If product was purchased under 340B Program)
 - 3) Debit Memo Details: Debit Memo Number, Debit Memo Date, Debit Memo Amount
 - 4) Product Details: Product Description, Quantity – Full or Partial, NDC Number, Lot Number, Expiration Date
- B. Amgen contracts with PharmaLink to manage the return and destruction of non-saleable products. To be eligible for credit, the Products must be returned to the address listed below and in accordance with the following procedures:

PharmaLink

Receiving Department PLI-AMG
8285 Bryan Dairy Road, #160
Largo, FL 33777

- 1) The Return Details listed in Section 5A above must be supplied or the RA Request will be declined, and Product will not be eligible for credit.
- 2) Prior Return Authorization (RA) is required for all returns. Requests for RA box



labels are made via PharmaLink's website www.PharmaLinkinc.com.

- 3) Issuance of RA does not guarantee credit. Credit issuance is dependent upon confirmed receipt and review of returned Products. Unauthorized return Products will be destroyed, and credit will not be issued.
 - 4) All returns must be received by Amgen's third-party processor, PharmaLink, no later than sixty (60) days after RA Label issuance and must include the RA Label attached on the exterior of the box and a copy of the Customer's Debit Memo for such return(s) enclosed in the shipment. Returns received post RA expiration will not be eligible for credit.
 - 5) For assistance in returning Amgen Product, contact Customersolutions@PharmaLinkinc.com
- C. The piece count to determine credit will be performed by either Amgen or Amgen's third-party processor and will be considered final.
 - D. Credit for eligible returns will be issued per Amgen terms noted herein unless state and local law requires otherwise.
 - E. Products that do not meet the criteria set forth in this Product Return Policy for return and credit may be sent to PharmaLink for disposal and destruction. For Customers returning through other third-party processors, Amgen will not issue credit if the third-party processor does not provide the required information to PharmaLink as noted in Sections 5A and 5B.
 - F. 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.
 - 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 Amgen or Amgen's returns processing agent, PharmaLink and are liable for the Product until Amgen or PharmaLink confirms receipt of Product.
 - H. For Products that are returned within the Expiration Window, Amgen will neither pay for nor reimburse any Customer (including ADR) for any return goods transportation costs, handling fees, or processing fees incurred on the part of the Customer or Customer's return goods processor. ADRs are specifically prohibited from deducting from any payment any such return transportation costs, handling fees or processing fees.
 - I. For all other eligible returned Product, cost of shipping shall be paid by Amgen.
 - J. Amgen is not responsible for return shipments lost in transit or received in damaged condition.
 - K. 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 creditmemo.
- B. For returns from non-ADR accounts, credit will be issued directly to returning Customer in the form of a 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, UTradeOpsReturns@amgen.com.