

# UroGen Pharma Inc. RETURN GOODS POLICY

The UroGen Pharma Inc. (UroGen) Return Goods Policy (Policy) governs the return of UroGen pharmaceutical products (Products) purchased directly from UroGen or a UroGen Authorized Distributor of Record (ADR) by entities licensed to dispense or administer Product in the United States (Customer) and third party returns processors in the United States (Returns Processor[s]) processing returns on behalf of ADRs and Customers. Examples of eligible entities under this Policy include ADRs, ambulatory surgical centers, hospitals, long term care facilities and clinics.

This Policy supersedes all other Return Goods Policies from United States distributors, wholesalers, pharmacies, retailers, clinics, and hospitals (collectively Entities). This Policy applies to all Entities, unless otherwise governed through an alternative agreement specifically between UroGen and an Entity (in which case the terms of the specific agreement shall dictate).

UroGen accepts returns and evaluates for applicable reimbursement, credit or replacement in accordance with this Policy, as it is in effect at the time of return. UroGen has sole discretion on final determination of reimbursement/credit or replacement for all Product returns.

A Return Goods Authorization (RGA) is required to return Products. Products will not be reimbursed, credited or replaced without an RGA, and reimbursement, credit or replacement will only be issued if it is within the terms of this Policy. RGAs expire sixty (60) calendar days from the date issued.

### 1. PRODUCT ELIGIBLE FOR RETURN

The following criteria define Product eligible for return consideration, all of which must be returned to UroGen:

- 1.1. Product must be directly purchased from UroGen or from an ADR
- 1.2. Product proof-of-purchase must be supplied by the eligible Entity upon request by the UroGen Returns Department
- 1.3. Product must be in the original Product packaging with Product seals and label and vial box seal intact; containing fully readable NDC (if applicable), bar code, lot number, and expiration date printed on each Product (the expiration date is defined as the last day of the month, e.g. 11/21 is fully expired on November 30, 2021). See section 9 for scenarios in which Product packaging has been opened.
- 1.4. Short Dated Product, which is product within 30 days of its expiration date, is eligible for return.

- 1.5. Product that is more than 30 days from its expiration date that is returned because a patient did not attend a scheduled appointment, or the patient's treatment was discontinued, or the Product was unused through no fault of UroGen and through no fault of the Customer.
- 1.6. Expired Product received must not be greater than thirty (30) days past the expiration date printed on each Product.
- 1.7. Product shipped directly that was damaged in transit before reaching the Customer, subject to FOB terms, or shipped in error by UroGen.
- 1.8. Product that is discontinued, withdrawn, or recalled.

#### 2. PRODUCT NOT ELIGIBLE FOR RETURN

Although all UroGen Products may be returned to UroGen, no reimbursement, credit, or replacement will be issued for:

- 2.1. Product with more than thirty (30) days remaining until the expiration date printed on each Product (except for Product described in Section 1.5 above).
- 2.2. Expired Product received by UroGen more than sixty (60) days past the expiration date printed on each Product.
- 2.3. Product where proof of purchase from UroGen or an ADR cannot be verified, either by Proof of Purchase (invoice) or EDI 867 Data from the ADR.
- 2.4. Product with unknown or unidentifiable lot number and/or serial number and/or expiration date on the original package.
- 2.5. Product not in original manufactured packaging (including, opened, altered or repackaged Product).
- 2.6. Product sold on a "non-returnable" basis.
- 2.7. Damaged Product (including but not limited to broken, shattered or smashed vials), where such damage occurred while in an ADR, Customer or Return Processor's possession (unless Product meets criteria listed in section 9 for scenarios in which Product packaging has been opened).
- 2.8. Product damaged from such perils as are normally insured including, without limitation, extended coverage, vandalism, malicious mischief, natural disasters (flood, hurricane, tornado, etc.), and improper storage and handling.
- 2.9. Distressed Product involved in fire, theft, or bankruptcy sale.
- 2.10. Product stored out of compliance with specifications or handled improperly where Customer knew or should have known proper storage and handling requirements for such Product.

- 2.11. Any opened Product, unless the opened Product meets criteria in section 9 for scenarios in which Product packaging has been opened.
- 2.12. Product obtained illegally or via diverted means including, without limitation, products imported from countries outside the United States or acquired for the sole purpose of returning to UroGen for credit.
- 2.13. Product that is adulterated, misbranded, diverted, illegally obtained or counterfeit, as determined by UroGen in its sole discretion.
- 2.14. Product samples or Product that was donated or part of any UroGen indigent care programs.
- 2.15. Product destroyed by ADR, Customer or Returns Processor without prior written authorization from UroGen.
- 2.16. Product in which Customer has requested or seeks to request reimbursement or credit from a patient or third party.
- 2.17. Product that is lost and cannot be located, without fault from UroGen.
- 2.18. Product not sent to UroGen or, if authorized for destruction, without a valid certificate of destruction.
- 2.19. Product returned without meeting Return Documentation Requirements defined in section 5 below.
- 2.20. Product returned without an RGA.

#### 3. BASIS OF REIMBURSEMENT OR CREDIT

All eligible Product returned in accordance with and subject to the terms and conditions set forth herein, are subject to valuation by UroGen in its sole discretion and reimbursed or credited per the following:

- 3.1. Return Product will be valued at the wholesale acquisition cost (WAC)\* at invoice date or applicable contract price, as determined by UroGen.
- 3.2. Reimbursements or credits will be issued through an ADR, unless the account purchases direct from UroGen.
- 3.3. Credits expire 12 months from date issued.
- 3.4. UroGen will neither issue reimbursements or credits or accept charges/deductions for administrative, handling, or freight charges associated with the return of the product to UroGen, nor for associated products (e.g., Administration Kits) or services (e.g., pharmacy mixing services) purchased as part of any Product purchase.
- 3.5. UroGen reserves the right to make the final determination on the valuation of the return.

3.6. Product is valued according to this Policy, as in effect at the time the Product is physically received at the UroGen Approved Returns Vendor.

# 4. PROCEDURE FOR RETURNING PRODUCT

4.1. All eligible Product returns that are shipped to UroGen require a Return Goods Authorization (RGA) to be eligible for reimbursement/credit/replacement according to the terms of the UroGen Return Goods Procedure. To obtain an RGA, fax or email the request to:

Fax: (614) 652-0271

Email: GMB-SPS-ReturnRequests@cordlogistics.com

4.2. All eligible Product returns being sent for reimbursement or credit consideration must be sent prepaid postage to UroGen, at the following address:

UroGen Attn: Returns Department

15 Ingram Blvd., Dock 43 LaVergne, TN 37086

- 4.3. Returns must be packed carefully and in compliance with all applicable federal, state and local laws, rules, and regulations. Each return shipment must contain a copy of a debit memo and issued RGA. If a return shipment has multiple boxes, photocopy the RGA form as needed and place one in each box, and affix the supplied UroGen RGA label to the outside of each shipping package.
- 4.4. Product must be returned to UroGen or, if authorized for destruction, a photograph of the Product bar code and certificate of destruction must be given in order to receive credit.
- 4.5. UroGen is not responsible for shipments lost or damaged in transit, for returns not received by UroGen, or for returns sent via multiple cartons under one Proof of Delivery (POD).
- 4.6. The sending Entity is responsible for any regulatory filing or reporting required for lost in transit shipments that occur prior to UroGen physical acknowledgment of actual receipt of Product.
- 4.7. No reimbursement or credit will be issued for shipping or handling costs incurred to return Product.

# 5. RETURN DOCUMENTATION REQUIREMENTS

- 5.1. All returns of Product must include a debit memo and RGA, as provided by UroGen. Product received without required information will be processed for destruction, and no reimbursement, credit, or replacement shall be issued.
- 5.2. The following information **must be provided for RGA requests** to be eligible for reimbursement:
  - 5.2.1. Valid originating Customer name and mailing address

- 5.2.2. Remit To name and mailing address for reimbursement by check (if applicable)
- 5.2.3. Current ADR for reimbursement via credit (if applicable)
- 5.2.4. Debit Memo Number, Purchase Order Number, or another unique identifier
- 5.2.5. Originating Customer Identification (HIN or NPI number)
- 5.2.6. Product NDC, as applicable
- 5.2.7. Lot Number, Expiration Date
- 5.2.8. Quantity
- 5.2.9. Item Description
- 5.2.10. Reason for return
- 5.2.11. Returning Entity Name who prepared and shipped the return (Return Processor, if applicable)
- 5.2.12. Identification of contract pricing and associated contract identifier (if applicable)
- 5.2.13. RGA number
- 5.2.14. Product returned that was purchased at a contracted price (examples: GPO and 340B) must include notation on the accompanying documentation that the Product was purchased at a contracted price and include all applicable identification (examples: HIN, HRSA assigned 340B identifier).

# 6. SPECIAL INSTRUCTIONS

- 6.1. Return Processors must comply with all requirements of this Procedure for Product returns to be accepted by UroGen for processing and reimbursement or credit consideration.
- 6.2. UroGen reserves the right to audit a Third-Party Return Processor who is processing on behalf of an Entity.
- 6.3. Return claims or disputes must be submitted to UroGen Returns via email at GMB-SPS-ReturnRequests@cordlogistics.com no later than six (6) months past UroGen issuing reimbursement or credit memo notification.
- 6.4. Serialized Product 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.
- 6.5. UroGen has the right to destroy any return Product in its custody.

# 7. PRODUCT RETURN QUESTIONS

For questions about Product returns, please contact UroGen Returns Customer Service via email at GMB-SPS-ReturnRequests@cordlogistics.com.

# 8. PRODUCT RECALLS

In the event of a Product recall, specific instructions shall be disseminated to the appropriate entities.

# 9. OPENED PRODUCT LOSS CLAIMS

Opened Product Loss Claims not arising under a UroGen Limited Warranty (see Paragraph 11 below) may be eligible for replacement on a patient-level basis to ensure appropriate patient care and treatment based on

the below requirements. Except as provided in Paragraph 9.8 below, Opened Product is not eligible for reimbursement/credit. To be eligible for replacement, the opened Product must have been:

- 9.1. Opened or mixed in anticipation for administration to a specific patient within a reasonable time (not more than eight hours) of patient's arrival or expected arrival at a Customer facility and not administered for reasons beyond the Customer's control due to the patient's unavailability or clinical reasons preventing administration of Product to the patient; or
- 9.2. Opened or mixed in anticipation for administration to a specific patient within reasonable time (not more than eight hours) of patient's arrival or expected arrival at a Customer facility and accidently dropped in the process resulting in breakage or contamination; or
- 9.3. Unusable due to Product preparation error by Customer in anticipation for administration to the patient; or
- 9.4. Unusable due to missing Product administration component; and
- 9.5. Not billed to or reimbursed by the patient or any third party; and
- 9.6. Not damaged from such perils as are normally insured including, without limitation, vandalism, malicious mischief, natural disaster, and improper storage; and
- 9.7. Approved Opened Product loss claim requests are subject to limitations applied per claim and per facility where Opened Product loss occurred. These limitations are set at UroGen's sole discretion. Opened Product must be destroyed per local requirements for hazardous material destruction. Do not send Opened Product back to the UroGen Return Center for processing. Provide photo and certificate of destruction. Material Safety Data Sheet (MSDS) is available from UroGen upon request.
- 9.8. Opened Product is not eligible for reimbursement/credit (i.e., only replacement may be offered), except when Customer requests reimbursement/credit for a loss claim on the Opened Product pursuant to subsections 9.1, 9.2, or 9.4 and UroGen determines, in its sole discretion, that Customer does not need replacement Product for patient care for the foreseeable future.
- 9.9. Please email GMB-SPS-ReturnRequests@cordlogistics.com for questions related to Opened Product Loss Claims and/or to initiate the claim process. A claim form will be provided after an initial evaluation of the Product loss event relative to the approval criteria as defined by the UroGen Return Goods Policy.
- 9.10. Replacement Product provided by UroGen to Customer is intended for administration to the same patient forwhich the Product was originally opened but not administered.

## 10. ADDITIONAL TERMS AND CONDITIONS OF RETURN GOODS POLICY

- 10.1. Any exception to this Policy must be authorized via the UroGen returns exception process and will be at UroGen's sole discretion.
- 10.2. Product that has been returned to UroGen cannot be sent back to the customer for any reason.
- 10.3. UroGen is not responsible for return shipments lost in transit or received damaged.
- 10.4. Products that do not qualify for reimbursement or credit will be destroyed and not returned to the customer.

- 10.5. UroGen reserves the right to request proof of purchase before issuing reimbursement, credit or replacement for returnable items. Proof of purchase includes standard industry product identifiers along with ADR name.
- 10.6. This Policy supersedes all previous UroGen Return Goods Policies. UroGen reserves the right to change, modify, amend, rescind, revoke, or terminate this Policy at any time, for any reasons, including without limitation, to comply with any applicable, laws, rules, regulations, or guidance, with or without notice.
- 11. UroGen Limited Warranty for Non-Conforming Product or Product Support Services
  - 11.1 UroGen warrants (a) the identity and the quality of ingredients used in the Product at the time of its manufacture and in the care and skill exercised in such Product's manufacture; and (b) the delivery of Product support services for Product acquisition, Product pharmacy preparation, and the transportation of prepared Product to Customer as described in Product labeling materials. UROGEN DOES NOT MAKE ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, OF ANY KIND, FOR PRODUCTS OR OTHER PRODUCT SUPPORT SERVICES (E.G., REIMBURSEMENT FOR PRODUCT OR REIMBURSEMENT SUPPORT FOR PRODUCT), INCLUDING WARRANTIES AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCTS OR PRODUCT SUPPORT SERVICES, OR CONCERNING INDICATIONS AND CONTRAINDICATIONS, DOSAGES USED, METHOD OF ADMINISTRATION OR CONDITIONS OF USE FOR SUCH PRODUCT. EXCEPT AS SET FORTH ABOVE, PRODUCT AND PRODUCT SUPPORT SERVICES ARE SOLD "AS IS".
  - 11.2 Credit/reimbursement or replacement may be considered by UroGen for Product returns based on the failure of the Product, Opened Product or Product Support Services to conform to the limited warranty set forth in paragraph 11.1.

<sup>\*</sup>UroGen Wholesale Acquisition Cost (WAC) is the listed price to the distribution channel not including prompt pay, service or administrative fees, stocking or distribution allowances or any discounts, rebates or chargebacks provided by UroGen to any entity.