LILLY RETURN GOODS PROCEDURE

The Lilly Return Goods Procedure (Procedure) governs the return of Lilly pharmaceutical product (Product) purchased directly from Lilly USA, LLC (Lilly) or a Lilly Authorized Distributor of Record (ADR) by entities licensed to dispense or administer Product (Customer) and third party returns processors (Returns Processor(s)) processing returns on behalf of ADRs and Customers. Examples of eligible entities under this Procedure include ADRs, retail and specialty pharmacies, hospitals, long term care facilities and clinics.

This Procedure applies to all noted United States entities unless otherwise governed through an alternative agreement with Lilly.

Lilly accepts returns and evaluates for applicable reimbursement in accordance with the Procedure in effect at the time of return. Lilly has sole discretion on final determination of reimbursement for all Product returns.

PRODUCT ELIGIBLE FOR REIMBURSEMENT

The following criteria define Product eligible for return reimbursement consideration:

1. Product directly purchased from Lilly or from a Lilly ADR.
2. Product with proof-of-purchase supplied upon request by Lilly Returns.
3. Product in the original Lilly container with label intact; containing fully readable NDC, bar code, lot number, and expiration date. For return of DEA Controlled Substances, Product must be in original Lilly trade retail packaging (outer carton).
4. **Expired** Product received not greater than one (1) year past expiration date except for Cyramza® (ramucirumab) and Portrazza® (necitumumab), which must be received not greater than six (6) months past expiration date.
5. Product does meet requirements defined for Reconstituted Product Loss Claim.
6. Product does **not** meet criteria defined as not eligible for reimbursement.

PRODUCT NOT ELIGIBLE FOR REIMBURSEMENT

Unless the Product meets the criteria specified above, it is not eligible for reimbursement. The following are conditions where no reimbursement will be issued for Product return:

1. Product received by Lilly Approved Returns Vendor more than one (1) year past the expiration date, or in the case of Cyramza and Portrazza, more than six (6) months past the expiration date.
2. Product where proof of purchase from Lilly or a Lilly ADR cannot be verified, either by Proof of Purchase (invoice) or EDI 867 Data from the ADR.
3. Product ordered in error or shipped in error by a Lilly ADR's downstream customer. In such circumstances, ADRs shall make proper adjustments according to the ADR's return policy and in accordance with state and federal law.
4. Product with unknown or unidentifiable lot numbers.
5. Product containing prescription labels.
6. Product not in original Lilly manufactured container.
7. Damaged Product (including but not limited to broken, shattered or smashed bottles, blister packs, pens or vials), where such damage occurred while in an ADR, Customer or Return Processor's possession (unless product meets return criteria in Reconstituted Product Loss Claim section below).
8. Product damaged from such perils as are normally insured including, without limitation, extended coverage,

vandalism, malicious mischief, natural disasters, and improper storage.

9. Distressed Product involved in fire, theft or bankruptcy sale.
10. Product stored out of compliance with specifications or handled improperly.
11. Any opened liquid Product or reconstituted Product, unless reconstituted product meets return criteria in Reconstituted Product Loss Claim section below.
12. Overfilled saleable unit container containing more Product than was originally packaged.
13. Product marked "Non-Returnable," such as Glucagon™ (glucagon for injection [rDNA origin]), "Professional Sample," "Professional Package," “Private Label” and "Clinical Trial Package," and/or with similar markings or special labels.
14. 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 Lilly for credit.
15. Product determined by Lilly to be counterfeit, diverted or obtained from suspected counterfeit distributors.
16. Product samples or Product that was donated or part of any Lilly indigent care programs.
17. Product manufactured to Customer specifications.
18. Product destroyed by ADR, Customer or Returns Processor.
19. Product returned by an ADR that was returned to them by their downstream Customer as unsaleable inventory (unsaleable by downstream customer and/or not able to be returned to ADR inventory for sale to another customer).
20. Product returned without meeting Return Documentation Requirements defined in section below.

BASIS OF CREDIT

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

1. Return Product will be valued at ninety percent (90%) of the lower of the wholesale acquisition cost (WAC)* at date of expiration or applicable contract price as determined by Lilly.
2. For open containers, reimbursement value will be based upon quantity of unused product returned.
3. Lilly is not responsible for processing fees and transportation expenses.
4. Eligible returns for reimbursement are exchangeable for either a check from Lilly or a credit issued to an ADR specified on return documentation. No checks or credit will be issued to a Returns Processor.
5. Lilly reserves the right to make the final determination on the valuation of the return.
6. Product is valued according to Procedure effective at the time the Product is physically received at the Lilly Approved Returns Vendor.
7. If credit reimbursement is issued to an ADR on behalf of the Customer noted on the return documentation, it is the ADR’s sole responsibility to reimburse the Customer. If the ADR is unable to issue credit to the Customer, the ADR has 90 days from the date of credit issuance to return funds to Lilly. If the funds are not returned within the defined period, it is the responsibility of the ADR to work with the associated Returns Processor to fund the return.

RETURN SHIPMENT INFORMATION

1. **Effective August 1, 2019**: **All Expired Product returns that are shipped to the Lilly Approved Returns Vendor, Qualanex, require a Return Authorization (RA) to be eligible for reimbursement according to the terms of the Lilly Return Goods Procedure.** To obtain a RA, email complete Debit Memo to customerservice@qualanex.com or visit Qualanex website to create a return authorization.

   Web: www.qualanex.com
   Fax: 847-775-7258
   Email: customerservice@qualanex.com

2. **Effective August 1, 2019**: All Expired Product returns being sent for reimbursement consideration must be sent prepaid postage to Qualanex, at the following address:

   Qualanex
   1410 Harris Road
   Libertyville, IL 60048

3. Returns should 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 RA. If a return shipment has multiple boxes, photocopy the RA form as needed and place one in each box, and affix the supplied Qualanex RA label to the outside of each shipping package.
4. All controlled substances must be packaged separately from non-controlled products.
5. Lilly is not responsible for shipments lost or damaged in transit or for returns sent via multiple cartons under one Proof of Delivery (POD).
6. Sending entity is responsible for any regulatory filing or reporting required for lost in transit shipments that occur prior to Qualanex physical acknowledgment of actual receipt of Product.

RETURN DOCUMENTATION REQUIREMENTS

1. All returns of Product must include a debit memo and RA as provided by Qualanex. Product received without required information will be processed for destruction, and no reimbursement shall be issued.
2. The following information **must be provided for RA requests** to be eligible for reimbursement:
   - Valid originating Customer name and mailing address
   - Remit To name and mailing address for reimbursement by check (if applicable)
   - Current ADR for reimbursement via credit (if applicable)
   - Debit Memo Number or other unique identifier
   - Originating Customer Identification (ex: DEA Registration #, HIN, or NPI)
   - Product NDC
   - Lot Number, Expiration Date
   - Quantity
   - Item Description
   - Returning Entity Name - who prepared and shipped the return (Return Processor, if applicable)
   - Identification of contract pricing and associated contract identifier (if applicable)
   - Returning Entity DEA Registration # (Required when returning Controlled Substance)
3. Each originating customer must be assigned a unique debit memo number.
4. 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: DEA Registration #, HIN and HRSA assigned 340B identifier).

SPECIAL INSTRUCTIONS

1. Return Processors must comply with all requirements of this Procedure for product returns to be accepted by Qualanex for processing and Lilly for reimbursement consideration.
2. Lilly reserves the right to audit a Third-Party Return Processor who is processing on behalf of a Lilly ADR or Customer.
3. Return claims or disputes must be submitted to Lilly Returns via email at returnedgoods@lilly.com no later than six (6) months past Lilly issuing credit memo notification.
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.
5. Lilly and Qualanex have the right to destroy any return Product in its custody.

EXPIRED PRODUCT RETURN QUESTIONS

For questions about **expired returns**, please contact Qualanex Customer Service at 800-505-9291 or email customerservice@qualanex.com**.** For questions regarding return reimbursement claims, please email returnedgoods@lilly.com.

PRODUCT RECALLS

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

RECONSTITUTED PRODUCT LOSS CLAIMS

1. **In date** reconstituted Product, which requires administration by a healthcare professional, may be eligible for reimbursement or product replacement in the event of product loss for Bona fide End Customers. For purposes of this procedure, the term "Bona fide End Customer" specifically excludes licensed distributors, third party processors and/or similar entities. Reimbursement or replacement will be considered based on below requirements. The Product was:
    a. reconstituted in anticipation for administration to the patient within reasonable time of patient arrival and not administered due to patient availability, clinical reasons or disease progression; or
    b. accidently dropped resulting in breakage; or
    c. unusable due to reconstituting execution error or mixing error in anticipation for administration to the patient; and
    d. properly stored; and
    e. not billed to or reimbursed by the patient or any third party; and
    f. not damaged from such perils as are normally insured including, without limitation, vandalism, malicious mischief, natural disaster, and improper storage
2. Approved product loss claim requests are subject to limitations applied per claim and per facility where product loss occurred. These limitations are set at Lilly's sole discretion.
3. Product that has been reconstituted must be destroyed per local requirements. **Do not send these products back to the Lilly Return Center or Lilly Approved Returns Vendor for processing.**

Please email lillytrade@lilly.com for questions related to Reconstituted 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 Lilly Return Goods Procedure.

APPLICATION OF PROCEDURE

Any exception to this Procedure must be authorized via the Lilly returns exception process and will be at Lilly's sole discretion.

Lilly reserves the right to change, modify, amend, rescind, revoke, or terminate this Procedure at any time, for any reasons, including without limitation, to comply with any applicable, laws, rules, regulations, or guidance, with or without notice.

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* Lilly USA's 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 Lilly USA to any entity.