



**INFUSED ONCOLOGY**

**PRODUCT RETURNS POLICY –**

**EARLY RETURNS PROGRAM**

**Effective Date: January 27, 2020**

The purpose of the Infused Oncology Product Returns Policy – Early Returns Program (“Policy”) is to allow Health Care Providers (HCPs) to return infused oncology products “early” (i.e. prior to expiry) for full credit provided all requirements in the Policy are met.

This Policy applies to Non-Resaleable, unexpired, infused oncology products distributed by JOM Pharmaceutical Services, Inc. (“JOM”) that are manufactured or marketed by a JOM Affiliate as listed at [www.jom.com](http://www.jom.com), and that are not subject to the Janssen Product Settlement Policy or eligible under a returns policy issued by the applicable wholesaler or distributor. (The return of Non-resaleable, expired infused oncology products may be eligible for full credit reimbursement under the standard JOM Return Goods Policy that can be found at [www.jom.com](http://www.jom.com).)

Under this Policy, Non-Resaleable, unexpired infused oncology products may only be returned directly to JOM from an eligible customer, as defined in section 2 of this Policy. At the date of its issuance, this Policy applies to the entire class of infused oncology products currently manufactured or marketed by any JOM Affiliate. JOM has the sole discretion to make the final determination of reimbursement for all returns.

JOM reserves the right to modify this Policy and its terms at any time, without notice, for any reasons, including, without limitation, all applicable Federal, State, and local laws, rules, regulations, ordinances, and directives. Any questions about this Policy should be directed to the JOM Customer Service Department (tel #1-800-631-5273) prior to making any return.

## **1. PRODUCTS ELIGIBLE FOR RETURN AND REIMBURSEMENT**

Under this Policy, infused oncology products are eligible for return and reimbursement only if all of the following criteria are met:

1. Product must be Non-Resaleable, as defined in Section 1.A. of this Policy;
2. Product must not be expired; and
3. Product must be returned for an eligible reason, as defined in Section 1.B. of this Policy.

### **A. Definition of Non-Resaleable Product**

Non-Resaleable product must meet at least one of the following:

- Product with an opened package and an unopened vial;
- Product with a damaged label and an unopened vial

Opened vials will **not** be eligible for return under this Policy.

## **B. Eligible Reasons for Return**

In order to be eligible for reimbursement or credit under this Policy, Non-Resaleable, unexpired, infused oncology products must be returned for one or more of the following reasons:

- Patient illness or death;
- Adverse event; or
- Patient's discontinuance of therapy.

## **C. Eligible Product Return Requirements**

Non-Resaleable, unexpired, infused oncology products eligible for return must meet all of the following criteria:

- Product must be Non-Resaleable, as defined in this Policy,
- Product must not be expired
- Product must be returned,
- The lot number and expiration date on the original container must be legible, complete, and unaltered,
- The product must have been purchased directly from JOM or an Authorized Distributor of Record ("ADR"), as evidenced by a proof of purchase upon request. A list of ADRs can be found at [www.jom.com](http://www.jom.com), and
- All returns must comply with state and federal laws and regulations.

## **2. CUSTOMERS ELIGIBLE TO RETURN INFUSED ONCOLOGY PRODUCTS**

Under this Policy, only the following customers may return Non-Resaleable, unexpired infused oncology products to JOM:

- Physicians;
- Infusion centers;
- Hospitals;
- Other healthcare providers; and
- Specialty pharmacies purchasing for use with a specific patient.

The following customers are not eligible to return Non-Resaleable, unexpired infused oncology products, because such entities are subject to separate returns agreements or arrangements:

- Wholesalers;
- Specialty Distributors;
- Retail pharmacies; and
- Specialty pharmacies not purchasing for a specific patient.

### **3. MONITORING AND AUDITING**

An appropriate plan for the monitoring and auditing of returns under this Policy shall be developed and implemented by JOM and the appropriate companies responsible for each of the infused oncology products. Expected volumes for returns shall be identified for each product subject to this Policy on an annual basis. If those volumes are exceeded, an audit shall be undertaken.

In addition, JOM and appropriate companies reserve the right to audit the amounts reimbursed for returned goods for a period of up to three years from when the payment or credit was issued. If the audit determines that a customer was paid/credited in excess of the amounts specified per the reimbursement policy, JOM will be allowed, at its election, to either: (1) withhold payments/credits for future returned goods; or (2) invoice the customer for the amount of the returned good overpayment and the customer must make payment within 30 days upon receipt of invoice.

### **4. CERTIFICATION**

In order to be eligible for reimbursement for any returned infusible oncology products covered under this Policy, the customer must certify that the product meets the Policy criteria by signing a certification letter as set forth in Attachment 1.

The certification letter must be signed by a health care provider who is licensed to prescribe and/or dispense infused oncology products on behalf of the end customer.

Reimbursement will not be made in connection with any request that is not properly certified by the customer.

### **5. PRODUCTS NOT ELIGIBLE FOR RETURN AND REIMBURSEMENT**

- Any products which do not meet the eligibility requirements described in Section 1 of this Policy.
- Product not purchased directly from JOM or an Authorized Distributor of Record (“ADR”), as evidenced by a proof of purchase upon request. A list of ADRs can be found at [www.jom.com](http://www.jom.com).
- Product in which the lot number and/or expiration date is altered, missing, illegible, covered, and/or unreadable on the original container.
- Product that has been damaged due to improper storage or handling, fire, flood, or catastrophe.
- Product container that is of mixed contents, including but not limited to strength/dosage or product family.
- Product that has been repackaged.
- Product that is labeled “sample”, “free goods”, “not for sale”, or similar designation.
- Partial vials, ampoules and syringes, or other partially used product.

- Product that has been involved in a sacrifice, fire, or bankruptcy sale.
- Product that has been sold expressly on a non-returnable basis.
- Product obtained illegally or via diverted means.
- Product that JOM determines, in its sole discretion, is otherwise adulterated, misbranded, or counterfeit.

## **6. PROCEDURE FOR RETURNING PRODUCT**

To initiate a Return Authorization (RA) Request, the customer should first contact the Janssen Medical Information Center (“MIC”) at tel # 1-800-526-7736, so that the MIC Representative can ascertain and record the reason for return, as well as the customer’s contact information. Each return request will be assigned a unique MIC Case #.

After collecting the information above, the MIC Representative will forward the following information to a JOM Specialist assigned to the MIC Case #: Customer Name, Customer tel # and/or e-mail address, product description and quantity of returns. Within two (2) business days, the JOM Specialist will confirm receipt of the Case # with the MIC and will contact the customer. The JOM Specialist will provide the customer with a copy of the Certification Letter (see Attachment 1) for signature. The JOM Specialist will also gather information from the customer in order to complete an RA Request form. Upon completing the RA Request form and receiving the signed copy of the Certification Letter from the customer, the RA Request will be approved. The JOM Specialist will provide the customer with the shipping instructions, pre-printed box shipping label(s) and a copy of the approved RA Request form. The pre-printed box shipping label(s) **must** be applied to every package that the customer returns. All product returns are to be shipped to:

**INMAR RX SOLUTIONS, INC.  
3845 GRAND LAKES WAY  
SUITE 125  
GRAND PRAIRIE, TX 75050**

All freight costs must be pre-paid by the customer.

All returned products must be sent to Inmar with the issued box shipping label applied, along with a copy of the approved RA Request form, which should be placed inside the box.

JOM will not be responsible for product that is destroyed (other than where such destruction occurs by the designated JOM vendor in compliance with instructions from JOM) and proof of destruction will not be accepted in lieu of an actual return. All eligible products must be shipped in a safe, secure, and reliable manner, and in compliance with all applicable federal, state and local laws, regulations and statutes.

It is the customer’s responsibility to securely package all return goods to prevent breakage during transit and to comply with laws and regulations applicable to the packaging, shipping, and transport of return goods shipments. Broken product containers that do not contain any viable

product are NOT eligible for return under this Policy. If any such containers are shipped they will be disposed of and will not be honored as a product return. If damaged, broken, wet and/or leaking shipping containers damaged during shipment are received, the product will be appropriately disposed of and no reimbursement will be made for the product to the customer.

JOM is not responsible for shipments lost and/or damaged in transit. JOM recommends that all customers insure return goods shipments.

## **7. REIMBURSEMENT**

All products, contracted and non-contracted, will be reimbursed, if eligible, based on the actual price paid by the applicable customer for the applicable product, excluding any distributor mark-up(s). This means that JOM will reimburse either at the actual price paid by the applicable customer or at JOM's average lot code selling price that the distributor paid for the item, whichever is lower. In order for JOM to properly credit the returned product, the customer must submit a copy of the original invoice associated with the purchase of the applicable product to JOM. If the customer cannot provide a copy of the original invoice, no credit will be awarded. The return credit will be given to the authorized Specialty Distributor or Wholesaler (as designated by the customer) and will be assigned to the customer. JOM reserves the right to adjust the reimbursement for any product at its sole discretion. If the original customer initiating the return cannot be verified based on information supplied with the return or upon request, no credit will be awarded. The terms of any contract between JOM or a JOM Affiliate and a Customer or ADR shall apply in addition to the terms of this Policy.

Any credits that are issued by JOM must be redeemed within one year of issuance; otherwise the credits may be voided or escheated in accordance with applicable law. If a non-direct purchasing customer cannot receive a credit via their current ADR, then the customer should contact JOM to determine an alternate method of reimbursement. Alternatively, if JOM cannot issue a credit to the non-direct purchasing customer's current ADR, then JOM will contact the customer to determine an alternate method of reimbursement.

Return goods shipments which are deemed to be outside of this policy will not be returned to the customer or Processor and no reimbursement will be issued by JOM for said product unless state or local law requires otherwise. In addition, JOM may deduct any associated costs for processing and destruction of the returned products from the total credit for the return.

## **8. EXCLUSIONS UNDER THIS POLICY**

This Policy does not apply to:

- Non-Resaleable, Expired Infused Oncology products; refer to the JOM Returns Goods Policy and the Return Goods Policy Product Listing ("RGPPL") at [www.jom.com](http://www.jom.com).
- Products manufactured or marketed by Patriot Pharmaceuticals, LLC; refer to [www.PatriotPharmaceuticals.com](http://www.PatriotPharmaceuticals.com) for more information.
- Products manufactured or marketed by Janssen Diagnostics, LLC.
- Recalled products; recalled product are subject to the specific terms of the recall notification.

- Divested products; divested products are subject to the specific terms of the divestiture notice. For a complete list of divested products, please refer to the RGPPL at [www.jom.com](http://www.jom.com).
- Products eligible for return under the applicable wholesaler's or distributor's returns policy.

This Policy does not address the issues addressed in the Janssen Product Settlement Policy. Please refer to the Janssen Product Settlement Policy for situations addressed in that document.

## **9. QUESTIONS ABOUT RETURNS**

Customers who are interested in the status of their product return should contact the assigned JOM Specialist directly. In the event that the customer contacts Janssen MIC regarding the status of the return, the MIC representative will transfer the customer to the assigned JOM Specialist.

For specific questions about this Policy, please contact the JOM Customer Service Department (tel # 1-800-631-5273).

**Attachment 1**

**Health Care Provider’s Certification Letter – Case # XXXXXX**

As a requirement for returning infused oncology products under the JOM Infused Oncology Product Returns Policy- Early Returns Program, the Certification Letter below must be completed in full and signed by the Health Care Provider requesting the return. The Certification Letter must be signed by a Health Care Provider who is licensed to prescribe and/or dispense infused oncology products, e.g. MD, DO, etc.

- I certify that I am currently authorized under the laws of the state where I am receiving credit or reimbursement for returned product to hold, prescribe and/or dispense prescription drugs. I further certify that the information provided in connection with the return of the infused oncology product(s) identified below is accurate and complete to the best of my knowledge and belief, and meets the requirements set forth in the Infused Oncology Product Returns Policy – Early Returns Program (“Policy”).
- I certify that the product I am returning meets the definition of “Non-Resaleable” Product under the Policy.
- I certify that I am returning a Non-Resaleable, unexpired, infused oncology product distributed by JOM Pharmaceutical Services, Inc. (“JOM”) that is manufactured or marketed by a JOM Affiliate and is listed below.

Check product being returned:

- DARZALEX®
- SYLVANT®
- YONDELIS®
- DOXIL®
- PROCRT®

- I certify that I am returning the infused oncology product due to at least one of the reasons listed below.

Check all reasons that apply.

- Patient Illness or Death
- Adverse Event
- Patient’s Discontinuance of Therapy

- I further certify that I have not and will not seek reimbursement directly or indirectly from any third party payer, including, but not limited to, any federal health care programs or any other source, such as the patient, for the returned product.
- I have not and will not resell any portion of the returned product pursuant to the Policy. I understand that the return does not involve any purchase obligation and that I am not required, as a condition of any return, to purchase, use, or recommend any Johnson & Johnson product at any time for any reason.

\_\_\_\_\_  
Signature of Health Care Provider

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Health Care Provider (PRINT)

\_\_\_\_\_  
Title of Health Care Provider

\_\_\_\_\_  
Name of Health Care Provider’s Practice / Clinic