Direct-to-Patient IP delivery during COVID-19 Pandemic SOP

Rivercity Pharmacy

Document Owner	Date of Issue	Version	Review date	Document No.	QCPP Ref.	QCPP Ver.
Pharmacy Practice Unit (PPU)	APR 2020	V1.0 (interim)	MAR 2021	ICONCTPRO20	N/A	N/A

Objective

To describe the procedures for couriering room temperature, oral Investigational Products (IP) directly to patients in response to the COVID-19 pandemic. Please note, this SOP is an interim version only and is subject to change in response to the evolving situation.

Scope

Rivercity Pharmacy are committed to working with Sponsors and ICON Research to ensure continuity of care for clinical trials patients throughout the duration of the COVID-19 pandemic. Where possible, patients enrolled in clinical trials will continue to receive supply of IP during their regularly scheduled clinic visits. However, given the uncertainty of the current situation and the rapidly evolving travel restrictions, the following procedure has been developed to address the need for direct-to-patient delivery of IP.

For patients that are required to self-isolate or are unable to attend site for regular dispensing visits during the COVID-19 pandemic, Rivercity Pharmacy will work closely with Sponsors and ICON Research to arrange for IP to be delivered directly to a patient's home. It is the expectation of Rivercity Pharmacy that the Sponsor is responsible for making all decisions regarding the courier service and temperature monitoring requirements of IP during direct-to-patient shipments. This would require the sponsor to engage the services of a reputable courier company who can offer a service that meets their specific requirements.

Once the sponsor has set up an account with their preferred courier and HREC approval has been granted, Rivercity Pharmacy will work directly with the courier company and the clinical trials coordinator (CTC) at site to arrange delivery to patients on a case-by-case basis. This would include providing delivery address information directly to the courier, coordinating a suitable delivery date with the patient and completing any necessary paperwork to document transport of IP.

The pharmacist or clinical trials coordinator would use the account information provided by the sponsor when booking a delivery with the courier to allow sponsor to be billed directly for this service. Rivercity Pharmacy would also charge an additional $72.50 per shipment to cover return postage bags and additional staff time required to complete this procedure.

Procedure

1. Upon completion of trial-specific mandated safety requirements, the CTC will alert the clinical trials pharmacist/technician if treatment will proceed and provide the appropriate signed prescription and or IXRS allocation as per Icon Research standard procedures.
2. The clinical trials pharmacist/technician will dispense and label the medication as per the trial protocol specifications and complete any relevant accountability logs.
3. Once labelled, a second pharmacy staff member will perform a check that the kits labelled match the IXRS allocation for the patient. The medication will be placed into a white delivery bag labelled with the patients name, address and date of delivery, along with any trial-related patient dosing diaries. A reply paid post bag will also be included to allow for patients to return all unused medications and dosing diaries from the previous cycle. This delivery bag will then be placed in a dedicated "for delivery" area within the pharmacy until collected by the courier.
4. When the courier arrives, the clinical trials pharmacist must confirm that the delivery address registered with the courier matches the patients name and address details on the bag prior to handing over to the courier.
5. The courier will place the bag into the provided shipping container. The shipping container will then be sealed in front of the pharmacist before being taken by the courier and delivered directly to the patient.
6. The pharmacist will record the date, time of collection and reply paid post bag tracking number on the "Direct-to-Patient IP Delivery Tracking Form" (See appendix 1)
7. Pharmacy will then send an email confirmation to the CTC to notify them of the successful collection as well as contact the patient by phone to notify them of the impending delivery. The pharmacist will brief the patient on the receipt process during this call and request that they contact pharmacy as soon as the delivery is received.
8. When the patient contacts pharmacy to confirm receipt of medication, the pharmacist will gather the following information from the patient.
    a. The time the delivery was received
    b. Whether the medications were received in good condition (i.e. no damage to packaging etc.)
    c. The kit numbers received match the IWRS allocation for the patient (if applicable)
    d. Confirm that the previous cycles unused medications and completed patient dosing diaries have been placed in the post bag provided for return to pharmacy.
9. Following the call, the pharmacist will record this information on the "Direct-to-Patient IP Delivery Tracking Form" before emailing the CTC to notify them of the successful receipt.
10. In the event that IP is damaged during shipment or does not match the IWRS allocation upon receipt, the pharmacist will contact the CTC immediately to determine a suitable course of action. If the pharmacist does not

receive a follow up call from the patient on the day the IP shipment is expected to be delivered, they will make all attempts to contact the patient prior to close of business and notify the CTC if they are unsuccessful.

If temperature monitoring is required during the above courier process, the sponsor must choose a courier company that is able to provide this service. In the event the courier includes the use of a temperature monitoring device during delivery, the following steps will be incorporated by the pharmacy team into the above process.

1. Upon collection by the courier, the pharmacist will record the temperature reading on the monitors display
2. The pharmacist will contact the patient directly to inform them that a temperature monitor will be included in the delivery. The patient will be asked to record the temperature displayed on the dial at time of receipt and communicate this to the pharmacist during the confirmation of receipt phone call.
3. The temperature at point of collection and at point of delivery will be recorded by the pharmacist on the "Direct-to-Patient IP Delivery Tracking Form"
4. If permissible by the courier company, the patient will be asked to keep the temperature monitor and return it to pharmacy in the included reply paid post bag along with any remaining unused IP from their previous visit.

In the event that sponsors are unable to source a suitable courier for direct-to-patient delivery, Rivercity Pharmacy can make arrangements to express post IP directly to patients using registered post bags. While temperature monitoring is not available with this service, this would enable for trackable delivery of IP directly to a patients home address. If a sponsor is in agreeance with this method of IP supply, they acknowledge that temperature monitoring is unable to be performed during transport and Rivercity Pharmacy cannot guarantee next day delivery using this method. Given this, express posting would only be suitable for room temperature IP that has sufficient stability data to support supply via this method. In the event a sponsor wishes to utilize this method of delivery, Rivercity Pharmacy would invoice the sponsor directly for any postage costs incurred. The procedure for express posting IP to patients would follow the same steps as outlined above for courier shipments.

APPENDIX 1

Direct-to-Patient IP Delivery Tracking Form

Clinical Trial Name: _____ Courier Name:_____

Site #: _____ Courier contact #: _____

PI: _____ Temperature monitor provided by courier: Yes □ / No □

Shipment Details						Recept Details			
Patient #/Initials	IP Bottles dispensed and/or IWRS allocation	Courier Reference or tracking number	Date and time of courier pick up/postage	Returns Express Post Bag Tracking # (for tracking returns)	Temp on collection (if applicable)	Date and time of receipt	IP received in good condition?	IP matches bottles dispensed and/or IWRS allocation	Temp on receipt (if applicable)