

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for INVESTIGATIONAL AGENT ORDERING

Policy:

Active CTEP registered investigators or their authorized shipping designees and ordering designees may order agents from the Pharmaceutical Management Branch (PMB), CTEP for NCI- sponsored or funded clinical trials using PMB-supplied agents.

Active CTEP-registered investigators and investigator-designated shipping designees and ordering designees must submit agent requests through the PMB Online Agent Order Processing (OAOP) application < <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp> >. Access to OAOP requires the establishment of a CTEP Identity and Access Management (IAM) account < <https://eapps-ctep.nci.nih.gov/iam/> > and the maintenance of an “active” account status and a “current” password.

• **Domestic Orders:**

- **All agent orders to domestic sites are shipped Monday through Thursday ONLY.** No shipments to domestic sites are available for Monday delivery.
- **Routine Open-Label Orders:** Standard PMB processing time is two (2) business days. There is no guarantee that agents will ship the same day that orders are received.
- **Expedited Open-Label Orders:** PMB provides next day delivery to registered investigators to meet "emergency" or urgent needs. **Requests for next day delivery must be received at PMB by 2:00 p.m. Eastern Time and the ordering site must provide an express courier account number.** Saturday delivery to domestic sites may be possible in special circumstances and must be discussed with PMB in advance. Saturday delivery service requests require an express courier account number provided by the ordering site.
- **Patient-Specific Orders:** Standard PMB processing time is two (2) business days. Patient-Specific orders require additional processing time and are not available for next day delivery. Saturday delivery to domestic sites may be possible in special circumstances and must be discussed with PMB in advance. Saturday delivery service requests require an express courier account number provided by the ordering site.

- **International Orders:**

- All orders require additional processing and shipment transit time and are not available for next day delivery. No shipments to Canadian sites are available for Monday delivery. Procedures will vary based on country of destination.

Guidelines:

- Protocol-Specific Orders:

- When a number of investigators are participating on a clinical study at the same institution, one investigator should be considered or designated the principal or lead investigator under whom all investigational agents for that protocol should be ordered.
- Order an eight week supply per enrolled study subject or as specified by the protocol.
- Sites should try to consolidate their order submission requests as much as possible. Do not submit separate orders for individual enrolled subjects.

- Patient-Specific Orders:

- Initial orders are submitted by the lead organization of the protocol and cannot be entered through OAOP.
- Subsequent orders must be submitted through OAOP, or as specified by the protocol, under the name of the investigator from the initial order.
- Per-order supply quantities will be defined in the protocol document.

- Orders will only be shipped to the investigator's designated shipping address. Investigators may only have a single shipping address. All changes to the investigator's shipping address must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.

- Changes or additions to investigator-designated shipping designees and ordering designees must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.

- The ordering designee submitting the order and the shipping designee will receive a confirmation e-mail of successful order submission. Order status may be viewed any time through the OAOP application. Upon shipment, a confirmation e-mail is sent which includes the order details and tracking information.

Questions or comments regarding investigational agent ordering should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) Monday through Friday between 8:30 am and 4:30 pm (ET) or email PMBAfterHours@mail.nih.gov anytime.